APPENDIX A — OPINION OF THE SUPREME COURT OF THE STATE OF MONTANA DATED, DECIDED AND FILED DECEMBER 28, 2000

No. 99-185

IN THE SUPREME COURT OF THE STATE OF MONTANA

2000 MT 381

LIBBY SLEATH, MARY ANN HAYES, GLENDA TRUESDELL, and MARY OWEN,

Plaintiffs/Appellants,

v.

WEST MONT HOME HEALTH SERVICES, INC., WEST MONT HOME MANAGEMENT SERVICES, INC., ORKIN EXTERMINATION COMPANY, INC., and EP CO., INC., and ROFAN SERVICES, INC., d/b/a DOWELANCO,

Defendants/Respondents.

APPEAL FROM: District Court of the First Judicial District, In and for the County of Lewis and Clark, The Honorable Jeffrey M. Sherlock, Judge presiding.

* * *

Heard January 11, 2000
Submitted February 15, 2000
Decided December 28, 2000

* * *

Appendix A

Justice James C. Nelson delivered the Opinion of the Court.

¶1 Appellants Libby Sleath, Mary Ann Hayes, Glenda Truesdell, and Mary Owen brought this personal injury action against Respondents West Mont Home Health Services, Inc. and West Mont Home Management Services, Inc. (collectively referred to as "West Mont"); Orkin Extermination Company, Inc. (Orkin); and Ep Co., Inc. and Rofan Services, Inc. d/b/a DowElanco (collectively referred to as "DowElanco"), for injuries Appellants allegedly suffered when Orkin applied a pesticide manufactured by DowElanco at the West Mont building where plaintiffs worked. The District Court for the First Judicial District, Lewis and Clark County, granted summary judgment in favor of DowElanco on the basis that Appellants' claims are preempted by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). We reverse and remand for further proceedings consistent with this opinion.

¶2 Appellants present the following issues for review:

¶3 1. Whether Appellants' failure to warn claims, pleaded in negligence, strict liability, and breach of express warranty, are preempted by FIFRA because they are based upon or implicate the pesticide's labels.

¶4 2. Whether the failure to warn claims in Appellants' negligence and strict liability theories of liability are preempted by FIFRA when Appellants were not purchasers or users of the pesticide and were, instead, unwitting bystanders who never saw the pesticide's labels and who suffered injury from the use of the pesticide by others.

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¶5 3. Whether Appellants' strict liability for design defect theory of liability is preempted by FIFRA.

¶6 Because we conclude that Issue 1 is dispositive, we do not address Issues 2 and 3.

Factual and Procedural Background

¶7 Appellants worked in a building in Helena owned by their employer, West Mont. Sometime in 1991, West Mont ordered that all windows in the building be closed and that the operating cranks for the windows be removed, thereby preventing fresh air ventilation of the building. Between 1991 and 1994, Orkin applied various pesticides, collectively referred to here as Dursban, to the interior of the West Mont building every three to six weeks without prior or subsequent warnings to Appellants. These pesticides were manufactured and sold by DowElanco.

¶8 Each of the Appellants began suffering from various physical ailments and were forced to leave their employment on advice of their physicians. Appellant Hayes worked in the West Mont building until June 28, 1993; Appellant Owen worked until July 12, 1993; Appellant Truesdell worked until August 24, 1993; and Appellant Sleath worked until May 1994. Appellants first learned that they were routinely exposed to Dursban in 1995 when they requested information from West Mont about the pesticide applications. Prior to 1995, Appellants were unaware that they had been exposed to Dursban.

¶9 Dursban is DowElanco's registered trademark for a group of insecticides developed, manufactured, and marketed by

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DowElanco. The active ingredient in each of the Dursban products is a synthetic chemical compound known as chlorpyrifos which is one of a group of compounds known as organophosphates. Organophosphates are synthetic chemical relatives of the nerve gases used in World Wars I and II. They are central and peripheral nervous system poisons that inhibit the action of the enzyme acetylcholinesterase.

¶10 Depending on exposure frequency and dosage levels, the toxicity to the central and peripheral nervous systems can cause symptoms such as headaches, dizziness, flu-like malaise, urinary frequency, confusion and difficulties with memory and concentration. Each of the Appellants exhibits one or more of these symptoms, all of which are toxicologically consistent with excessive exposure to chlorpyrifos as contained in Dursban.

¶11 Dursban's labels are registered in accordance with FIFRA and its implementing regulations. Each of the Dursban labels relevant to this case contains the following statement:

> DowElanco warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below.

¶12 DowElanco markets and sells its Dursban products only to professional applicators, distributors, and formulators. It does not market or sell Dursban products to the general

public. In fact, Dursban's labels require that it be applied by, or under the direction of, commercial applicators.

¶13 On January 5, 1996, Appellants filed a complaint against West Mont, Orkin, and DowElanco. Thereafter, on October 9, 1996, Appellants, with leave of the District Court, filed their Second Amended Complaint wherein they alleged that West Mont was negligent for failing to ensure that the building in which Appellants were working was free from hazardous chemicals and for failing to warn Appellants and other employees about the possible health risks of the pesticides applied in the building. Appellants also alleged that Orkin negligently and carelessly failed to give warning or otherwise take steps to ensure that Appellants and others would not be exposed to the pesticide's adverse effects.

¶14 As to DowElanco, the complaint alleged negligent design and manufacture of Dursban, strict products liability for the design and manufacture of Dursban, and breach of express and implied warranties. Moreover, the negligence and strict liability theories contained allegations that DowElanco failed to provide adequate warnings about the dangers of Dursban.

¶15 During the course of discovery, DowElanco served each Appellant with an identical set of 15 interrogatories. Appellants' answers to these interrogatories were nearly identical. And, in response to many of these interrogatories, Appellants referred to Dursban's labels.

¶16 On February 24, 1998, DowElanco moved for summary judgment on the basis that all of Appellants' claims are

preempted by FIFRA because Appellants' complaint and interrogatory answers show that Appellants' theories of liability are all based solely upon inclusions in or omissions from Dursban's labels. The specific provision in FIFRA to which DowElanco refers is 7 U.S.C. § 136v(b), which provides:

> (b) Uniformity
>
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

¶17 Appellants responded to DowElanco's motion for summary judgment by redacting their interrogatory answers to exclude specific references to Dursban's labels. Appellants also submitted a supplemental affidavit from Robert K. Smith, Ph.D., one of Appellants' proposed expert witnesses, setting forth his opinion that Dursban is defective and unreasonably dangerous "in the context of interior workplace application of those products."

¶18 DowElanco moved to strike this supplemental affidavit, but the District Court denied the motion. The court determined, however, that even considering the supplemental affidavit and excluding references to Dursban's labels in Appellants' interrogatory answers, all of Appellants' claims are based on Dursban's labels. Hence, the District Court concluded that pursuant to this Court's opinion in *McAlpine v. Rhone-Poulenc Ag. Co.* (1997), 285 Mont. 224, 947 P.2d 474, all of Appellants' claims against DowElanco are

preempted by FIFRA. Accordingly, the District Court granted summary judgment in favor of DowElanco.

Standard of Review

¶19 Our standard of review in appeals from summary judgment rulings is *de novo. Oliver v. Stimson Lumber Co.*, 1999 MT 328, ¶ 21, 297 Mont. 336, ¶ 21, 993 P.2d 11, ¶ 21 (citing *Motarie v. N. Mont. Joint Refuse Disposal* (1995), 274 Mont. 239, 242, 907 P.2d 154, 156; *Mead v. M.S.B., Inc.* (1994), 264 Mont. 465, 470, 872 P.2d 782, 785). When we review a district court's grant of summary judgment, we apply the same evaluation as the district court based on Rule 56, M.R.Civ.P. *Oliver*, ¶ 21 (citing *Bruner v. Yellowstone County* (1995), 272 Mont. 261, 264, 900 P.2d 901, 903). We set forth our inquiry in *Bruner* as follows:

> The movant must demonstrate that no genuine issues of material fact exist. Once this has been accomplished, the burden then shifts to the non-moving party to prove, by more than mere denial and speculation, that a genuine issue does exist. Having determined that genuine issues of fact do not exist, the court must then determine whether the moving party is entitled to judgment as a matter of law. We review the legal determinations made by a district court as to whether the court erred.

Oliver, ¶ 21 (quoting *Bruner*, 272 Mont. at 264-65, 900 P.2d at 903).

¶20 Moreover, in a summary judgment proceeding, the evidence must be viewed in the light most favorable to the nonmoving party, and all reasonable inferences will be drawn therefrom in favor of the party opposing summary judgment. *Oliver*, ¶ 22 (citing *Joyce v. Garnaas*, 1999 MT 170, ¶ 8, 295 Mont. 198, ¶ 8, 983 P.2d 369, ¶ 8). Consequently, we will view the evidence in the light most favorable to the Appellants and all reasonable inferences will be drawn in their favor.

Issue 1.

¶21 *Whether Appellants' failure to warn claims, pleaded in negligence, strict liability, and breach of express warranty, are preempted by FIFRA because they are based upon or implicate the pesticide's labels.*

¶22 The United States Constitution provides that "[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "It is basic to this constitutional command that all conflicting state provisions be without effect." *Maryland v. Louisiana* (1981), 451 U.S. 725, 746, 101 S.Ct. 2114, 2128-29, 68 L.Ed.2d 576 (citing *McCulloch v. Maryland* (1819), 17 U.S. 316, 427, 4 Wheat. 316, 4 L.Ed. 579; *Hines v. Davidowitz* (1941), 312 U.S. 52, 61 S.Ct. 399, 85 L.Ed. 581).

¶23 This preemptive power is not to be found carelessly, however.

> [B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," . . . we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."

Medtronic, Inc. v. Lohr (1996), 518 U.S. 470, 485, 116 S.Ct. 2240, 2250, 135 L.Ed.2d 700 (quoting *Rice v. Santa Fe Elevator Corp.* (1947), 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447). *See also Cipollone v. Liggett Group, Inc.* (1992), 505 U.S. 504, 516, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407. Thus, the purpose of Congress "is the ultimate touchstone" in every preemption case. *Medtronic*, 518 U.S. at 485, 116 S.Ct. at 2250 (quoting *Retail Clerks v. Schermerhorn* (1963), 375 U.S. 96, 103, 84 S.Ct. 219, 223, 11 L.Ed.2d 179).

¶24 Congress's intent may be "explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Cipollone*, 505 U.S. at 516, 112 S.Ct. at 2617 (quoting *Jones v. Rath Packing Co.* (1977), 430 U.S. 519, 525, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604). Furthermore,

> [i]n the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law, or if federal

> law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.

Cipollone, 505 U.S. at 516, 112 S.Ct. at 2617 (internal quotations and citations omitted).

¶25 FIFRA was first enacted by Congress in 1947 to regulate pesticides. The 1947 Act required pesticide manufacturers to register pesticides with the Secretary of Agriculture, to display poison warnings on the labels of highly toxic pesticides, and to include other warning statements to prevent injury to people, animals and plants. In 1949, the Secretary of Agriculture, under the authority of FIFRA, issued substantial pesticide labeling requirements. In 1970, the authority for pesticide regulation was transferred to the newly created Environmental Protection Agency (EPA), which now administers the pesticide labeling requirements imposed by the Department of Agriculture.

¶26 In 1972, Congress enacted sweeping amendments to FIFRA, largely in response to public concerns over the health risks of the pesticide DDT. The 1972 amendments established that the primary purpose of federal pesticide regulation is the protection of human health and the environment from the risks posed by pesticides. While FIFRA had previously regulated pesticides primarily through labeling requirements, the 1972 amendments established federal regulation of pesticide use, an area previously regulated exclusively by the states.

¶27 The 1972 amendments established a program of federal-state cooperation in regulating pesticides. Under this

program, the EPA registers pesticides for a particular use and approves pesticide labels. In doing so, FIFRA requires that the EPA must determine whether the pesticide's composition is such as to warrant the proposed claims for it; whether the labeling and other materials comply with FIFRA; whether the pesticide will perform its intended function without unreasonable adverse effects on the environment; and whether the pesticide will have unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practices. Pursuant to a 1978 amendment, the EPA does not evaluate pesticide label claims regarding efficacy or otherwise regulate efficacy in approving pesticide labels.

¶28 States retain broad authority to regulate the sale and use of pesticides. Under 7 U.S.C. § 136v(a), states may regulate pesticide sales or use more strictly than the federal government. Under 7 U.S.C. § 136v(c) and its accompanying regulations, states may register pesticides for local uses in addition to those approved by the EPA and may impose supplemental labeling requirements regarding those additional uses.

¶29 The term "label" means "the written, printed, or graphic matter on, or attached to, the pesticide . . . or any of its containers or wrappers." 7 U.S.C. § 136(p)(1). The term "labeling" means "all labels and all other written, printed, or graphic matter — (A) accompanying the pesticide . . . at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide. . . ." 7 U.S.C. § 136(p)(2). The EPA has specific regulations concerning content, placement, type size, and prominence of warnings

and precautionary statements on a label. See 40 C.F.R. § 156.10. The final form of the printed labeling for a pesticide must be submitted to and accepted by the EPA before registration. 40 C.F.R. § 156.10(a)(6). Once the EPA approves a label, the manufacturer may not change it without the EPA's approval. *Worm v. American Cyanamid Co.* (4th Cir. 1993), 5 F.3d 744, 747.

¶30 In the case *sub judice,* Appellants ask this Court to revisit its decision in *McAlpine v. Rhone-Poulenc Ag. Co.* (1997), 285 Mont. 224, 947 P.2d 474, insofar as it holds that state law claims based on a failure to warn are preempted by FIFRA to the extent that they expressly or implicitly challenge the adequacy of the warnings in a pesticide's label. Appellants maintain that this Court reached its conclusion in *McAlpine* by following the decisions holding that the preemption language of FIFRA should be given the same effect as the statute governing cigarette advertising that the United States Supreme Court construed in *Cipollone v. Liggett Group, Inc.* (1992), 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407.

¶31 Appellants present three reasons why we should revisit our decision in *McAlpine.* First, Appellants argue that a plain reading of the parties' briefs in *McAlpine* confirms that all parties to that appeal simply assumed that *Cipollone* was controlling on the question of FIFRA's preemption language and never examined the validity of that proposition.

¶32 Second, Appellants point out that none of the parties' briefs in *McAlpine* mentioned *Medtronic, Inc. v. Lohr* (1996), 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700, wherein the

Supreme Court stated that the preemption language of the Medical Device Amendments of 1976 (the MDA), which is similar to FIFRA's preemption section, does not preempt state law failure to warn claims regarding medical devices even though they are properly labeled pursuant to the MDA. *Medtronic*, 518 U.S. at 501-02, 116 S.Ct. at 2258. Appellants argue that *Medtronic* demonstrates that when a federal regulatory statute consistently uses the term "requirement" to mean positive legislative or administrative enactments, and there is no indication in the statute's legislative history that Congress intended to preempt state common law, the term "requirements" does not include common law damage actions.

¶33 Third, Appellants point out that the United States Department of Justice, representing the EPA, filed an *amicus curiae* brief in *Etcheverry v. Tri-Ag Service, Inc.* (Cal. 2000), 993 P.2d 366, articulating the Government's position that FIFRA does not preempt any state law theories of liability, including failure to warn claims that implicate pesticide labels. Appellants argue that the EPA's view of the scope of FIFRA's preemptive effect is entitled to substantial weight because the EPA is charged by Congress with overseeing the primary enforcement responsibility of the states under FIFRA, and thus the EPA is uniquely qualified to determine whether a particular form of state law should be preempted. Appellants also argue that the EPA's brief is a record of the California Supreme Court within the meaning of Rule 202(b)(6), M.R.Evid., and that this Court may take judicial notice of it pursuant to Rules 202(d)(2) and (f)(2), M.R.Evid.

¶34 DowElanco argues on the other hand, that Congress expressly stated its intent to preempt state law under FIFRA when it amended § 136v(b) in 1972 to read:

> [A] State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act.

In addition, DowElanco maintains that Appellants' argument that this Court was inadequately advised when it decided *McAlpine* has been waived by Appellants' failure to raise the argument in the District Court and that, even so, Appellants' argument is without merit. DowElanco argues that the United States Supreme Court's decision in *Medtronic,* wherein the Supreme Court construed a different statute, does not alter preemption analysis under FIFRA. Moreover, DowElanco argues that even though *Medtronic* was decided nearly two years before Appellants filed their response to DowElanco's motion for summary judgment, Appellants did not make any argument to the District Court based on *Medtronic* or even cite to *Medtronic* in their response to DowElanco's motion for summary judgment. Hence, DowElanco contends that Appellants waived their *Medtronic* argument.

¶35 DowElanco correctly points out that this Court has repeatedly held that we will not address either an issue raised for the first time on appeal or a party's change in legal theory. *Unified Industries, Inc. v. Easley*, 1998 MT 145, ¶ 15, 289 Mont. 255, ¶ 15, 961 P.2d 100, ¶ 15. However, this Court has never applied this rule to cases. Indeed, we have decided

issues based on cases neither side cited. *See DeTienne Associates v. Montana Rail Link*, (1993), 261 Mont. 238, 241, 862 P.2d 1106, 1107-08. *Medtronic* does not raise an issue for the first time on appeal or raise a new theory of liability. It simply represents further legal support for the preemption issue. "In our *de novo* review of a district court ruling on summary judgment, we are not bound by the legal authority presented in the district court." *Thomas v. Northwestern Nat. Ins. Co.*, 1998 MT 343, ¶ 22, 292 Mont. 357, ¶ 22, 973 P.2d 804, ¶ 22.

¶36 DowElanco also objects to Appellants' contention that this Court should consider and give deference to the EPA's brief in *Etcheverry*. DowElanco maintains that courts do not give deference to an agency's statutory interpretation which is contrary to the plain language of a statute, as determined by the courts. DowElanco argues that Appellants have put the cart before the horse because the initial question is whether Congressional intent can be ascertained by the language of the statute and traditional tools of statutory interpretation. Moreover, DowElanco argues that the rule of deference to agency statutory interpretations does not apply to an agency's litigation position.

¶37 In *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.* (1984), 467 U.S. 837, 844, 104 S.Ct. 2778, 2782, 81 L.Ed.2d 694, the United States Supreme Court stated: "We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer. . . ." In this case, because the EPA is the agency charged with administering FIFRA, we agree with Appellants that we

should consider the EPA's brief in *Etcheverry* and that the EPA's interpretation of FIFRA should receive deference.

¶38 Moreover, the EPA was not a party in any of the previous actions regarding FIFRA and had not previously expressed an opinion in court on whether FIFRA preempts state-law damages actions. As a result, we did not have the benefit of the EPA's position on FIFRA preemption when we decided *McAlpine*. Nor did we have the benefit of the United States Supreme Court's decision in *Medtronic*. Consequently, we take this opportunity to revisit our decision in *McAlpine* insofar as it holds that state law claims based on a failure to warn are preempted by FIFRA.

¶39 In *McAlpine*, several farmers brought a products liability action against the manufacturer and distributor of a herbicide alleging that they suffered damage as a result of defendants' failure to warn them that the herbicide could damage their crops if applied in cool weather. We held in *McAlpine*, that because the plaintiffs' negligence claim was based solely on the insufficiencies in the product's warning label, that claim was preempted by FIFRA. *McAlpine*, 285 Mont. at 231-32, 947 P.2d at 478. We also held that FIFRA did not preempt plaintiffs' breach of warranty and strict liability claims to the extent that those claims did not rely on representations made on the product's label. *McAlpine*, 285 Mont. at 232-33, 947 P.2d at 478-79.

¶40 We predicated our decision in *McAlpine* on the United States Supreme Court's decision in *Cipollone* wherein the Supreme Court interpreted a portion of the Public Health Cigarette Smoking Act of 1969 that provided:

> (b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

Cipollone, 505 U.S. at 515, 112 S.Ct. at 2617 (quoting 15 U.S.C. § 1334(b)).

¶41 The plaintiff in *Cipollone* claimed that the defendant tobacco company caused his mother's death by failing to provide adequate warnings on its cigarettes and by misrepresenting the dangers of smoking to the public. *Cipollone*, 505 U.S. at 508, 112 S.Ct. at 2613. The Supreme Court determined in *Cipollone* that:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law: to the contrary, those words easily encompass obligations that take the form of common-law rules.

Cipollone, 505 U.S. at 521, 112 S.Ct. at 2620. On that basis, the Supreme Court held that state law failure to warn claims are preempted insofar as they require a showing that a defendant's cigarette advertising "should have included additional, or more clearly stated, warnings." *Cipollone*, 505 U.S. at 524, 112 S.Ct. at 2621.

¶42 In our discussion of *Cipollone* in *McAlpine*, we noted that

> [a]ll of the circuit courts, and several state supreme courts, that have considered the effect of FIFRA's preemption clause have concluded that it should be given the same effect as the preemption clause interpreted in *Cipollone* . . . . Thus, for purposes of determining the scope of FIFRA preemption, *Cipollone* provides the appropriate framework for our analysis.

McAlpine, 285 Mont. at 229-30, 947 P.2d at 477 (citations omitted). Hence, we determined in *McAlpine* that, as in the cigarette labeling statute at issue in *Cipollone*, the phrase "requirement" in § 136v(b) of FIFRA includes state common law damage actions. *McAlpine*, 285 Mont. at 230, 947 P.2d at 477. Consequently, we concluded that FIFRA preempts state tort claims to the extent that they arise from an omission or inclusion in a product's label, but that claims alleging a product, manufacturing, or design defect; claims alleging negligent design, testing, or manufacturing; or claims alleging breach of warranty that do not rely on such an omission or inclusion in the product's label, are not preempted. *McAlpine*, 285 Mont. at 230, 947 P.2d at 477.

¶43 However, as pointed out by Appellants in their brief on appeal and as we noted earlier in this opinion, we did not have the benefit of the Supreme Court's decision in *Medtronic* in making our determination in *McAlpine*. The Supreme Court held in *Medtronic* that in spite of its earlier decision in *Cipollone*, the preemption provision at issue in *Medtronic* did *not* preempt state common law damage actions.

¶44 In *Medtronic*, a pacemaker recipient's pacemaker failed resulting in a "complete heart block" that required her to undergo emergency surgery. According to her physician, the likely cause of the failure was a defect in the lead that transmits the heartbeat-steadying electrical signal from the "pulse generator" to the heart itself. The pacemaker recipient brought an action against the pacemaker manufacturer asserting claims of negligence and strict liability. *Medtronic*, 518 U.S. at 480-81, 116 S.Ct. at 2248.

¶45 The preemption statute at issue in *Medtronic* provided:

> State and local requirements respecting devices
>
> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Medtronic, 518 U.S. at 481-82, 116 S.Ct. at 2248-49 (quoting 21 U.S.C. § 360k(a)).

¶46 A four-Justice plurality held in *Medtronic* that distinct features of the MDA mandated the conclusion that Congress intended only to preempt states from imposing positive law "requirements" on medical devices in the form of regulations or laws and did not intend to preempt common law damage actions. *Medtronic*, 518 U.S. at 488-89, 116 S.Ct. at 2252. The *Medtronic* plurality found five key differences in the statutory schemes of the 1969 Cigarette Act and the MDA that mandated the conclusion that Congress did not intend the word "requirements" to mean the same thing in both statutes.

¶47 First, the preemption of state authority resulting from the 1969 Cigarette Act prevented only "a limited set of state requirements" — requirements imposed on advertising regarding the health effects of cigarettes, while preemption of common law actions as a result of the MDA would extinguish all state law design defect claims regarding all medical devices. Second, the MDA provided no private damages action that would replace state common law actions. Third, the MDA's preemption provision, unlike the 1969 Cigarette Act's, expressed congressional concern "with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions." Fourth, unlike the 1969 Cigarette Act, the MDA uses the word "requirements" in numerous provisions, and each use clearly refers only to statutory and regulatory law, not common law. Fifth, the legislative history of the MDA reveals no reference in the hearings, committee reports, or debates that suggests a congressional intent to preempt all common- law remedies. *Medtronic*, 518 U.S. at 487-91, 116 S.Ct. at 2251-53.

¶48 In the same way, while the term "requirements" may encompass common law duties in some contexts, the text, legislative history, and purposes of FIFRA demonstrate that Congress had no intent that the use of the term "requirements" in § 136v(b) would extinguish state common law damage actions. As the EPA noted in its *amicus* brief in *Etcheverry:*

> When § 136v(b) was enacted in 1972, state law actions against pesticide manufacturers for failure to warn were a commonplace and uncontroversial feature of the legal landscape. No evidence from the text or legislative history of FIFRA suggests that Congress had any intent to extinguish those actions or that Congress even considered doing so. Indeed, Congress amended FIFRA in 1972 out of increasing concern for the human health and the environmental effects of pesticides such as DDT. Given that FIFRA establishes no private damages remedy for those injured by pesticides, it would be astonishing that, without any discussion, Congress could have intended to deprive injured persons of all means of relief.

¶49 FIFRA's text demonstrates that Congress had no intent to extinguish damages remedies under state common law. For example, in § 136v, Congress used the term "requirements" to mean "regulation," a term connoting positive commands of law, not court orders to pay damages for the harms caused by pesticides. Section 136v(a) provides that "[a] State may regulate" the sales or use of pesticides as long as the state "regulation" does not permit a sale or use

prohibited by FIFRA. Section 136v(b) forbids "[s]uch state" from regulating labeling by imposing labeling "requirements" in addition to or different from those required under FIFRA. The plainest reading of the two subsections is that a state may "regulate" pesticide sales or use, but in doing so may not impose labeling "requirements." In other words, § 136v(b)'s prohibition on state labeling "requirements" represents an exception to § 136v(a)'s general grant of state authority to "regulate" pesticide sales and use.

¶50 The *Medtronic* plurality interpreted the term "requirements" in the MDA's preemption provision by examining its usages throughout the MDA. In doing so, the plurality adhered to "the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning." *Sullivan v. Stroop* (1990), 496 U.S. 478, 484, 110 S.Ct. 2499, 2504, 110 L.Ed.2d 438 (internal quotations and citations omitted).

¶51 The term "requirements" appears in FIFRA 75 times. No court considering preemption under FIFRA ever addressed the meaning of "requirements" in the entire context of FIFRA; courts only looked at it in terms of § 136v(b). However, in each instance other than § 136v(b), Congress intended the term "requirements" to mean enactments of positive law by legislative or administrative bodies. It is inconceivable that Congress intended that § 136v(b) would be the only section of FIFRA in which the term "requirements" includes the application of general rules of common law by judges and juries.

¶52 Throughout FIFRA, the term "requirements" refers exclusively to positive enactments of statutory and regulatory

law. Accordingly, the term "requirements" should be given the same reading in § 136v(b). Simply because the term "requirement" was found in *Cipollone* to encompass common law actions for damage, does not preclude this Court from reaching a contrary result in this case. "Only mischief can result if [the same words appearing in different statutes] are given one meaning regardless of the statutory context." *Lee v. Madigan* (1959), 358 U.S. 228, 231, 79 S.Ct. 276, 278, 3 L.Ed.2d 260.

¶53 Moreover, subsections (a) and (c) of § 136v demonstrate that Congress intended to authorize states to take actions that may indirectly prompt pesticide manufacturers to change their labels. Indirect pressure on pesticide manufacturers to change their labels, which may result from liability in damage actions, cannot be characterized as labeling "requirements." A state court award of damages for failure to warn does not mandate any change in labeling. Rather, it merely requires that a pesticide manufacturer pay money to an injured person. While a damage award may prompt a pesticide manufacturer to seek the EPA's approval for a change in labeling, it does not directly command such a change. As the EPA points out, such indirect pressure cannot reasonably be characterized as imposing labeling requirements.

¶54 Indeed, indirect pressure to change a pesticide label does not frustrate Congress's purpose of establishing nationally uniform pesticide labels. The EPA approves only one label per pesticide. In approving a labeling change, the EPA substitutes a new nationally uniform label. This process is the same whether the labeling change is prompted by state damage liability or state regulation authorized by FIFRA.

¶55 In addition, FIFRA's legislative history does not demonstrate a Congressional intent to extinguish actions for damages. As the EPA noted in its *amicus* brief, when § 136v(b) was enacted, common law actions against pesticide manufacturers for failure to warn were a "well-recognized and uncontroversial feature of the legal landscape." Common law actions for inadequate, misleading, or false representations regarding pesticides were available as early as 1884. And, in the first part of this century, dozens of reported decisions recognized the availability of actions for false or inadequate representations regarding pesticides, including actions based on pesticide labels. After FIFRA was enacted in 1947, the federal government issued substantial labeling regulations, but state and federal courts uniformly concluded that the federal pesticide labeling regulations did not alter the availability of state law damage actions for inadequate labeling. By 1972, when § 136v(b) was enacted, nearly every state and federal jurisdiction recognized pesticide manufacturer and dealer liability both for personal injuries and crop damage resulting from the failure to provide adequate warnings.

¶56 FIFRA's legislative history reveals no intent to alter the availability of common law remedies. In 1971 and 1972, three House and Senate committees devoted 25 days to hearings on proposed pesticide legislation. In the thousands of pages of transcripts of the hearings and floor debates, there is no suggestion that the 1972 amendments to FIFRA would preempt state tort law.

¶57 For instance, in the committee hearings, testifying on behalf of the Administration and the EPA, which drafted the

bill that formed the basis of the 1972 amendments, the EPA's General Counsel, John Quarles, testified as follows:

> I would like to emphasize that the States have played a major and continuing role in pesticides regulation. . . . We wish to encourage and not supplant these efforts by providing that States may prohibit the use of a particular pesticide within their jurisdiction even if the pesticide is registered under the Federal authority. States thus are not precluded from imposing stricter standards or added requirements, but they may not permit any sale or use of a pesticide which is prohibited under the authority of the Act.

The EPA's brief in *Etcheverry* at 24-25 (quoting the Federal Pesticide Control Act of 1971: Hearings Before the House Committee on Agriculture, 92d Congress (1971) at 8).

¶58 These hearings reveal that Congress had no intent to preempt state tort law. Quarles testified as the first witness in the first hearing, stating unequivocally: "The bill does not affect tort liability." EPA's brief at 28 (quoting House Ag. Comm. Hearing at 42). No one disagreed and no witness or member of Congress suggested that FIFRA would alter common law duties or affect the availability of tort damages.

¶59 In addition, the four House and Senate Committee reports describe in detail the changes that the 1972 amendments would bring to federal pesticide regulation. Each report summarizes the changes made by the bill, but none mentions any intent to preempt state damage actions.

¶60 Furthermore, the House and Senate debated the 1972 FIFRA amendments over 5 days. Like the committee hearings and reports, the floor debates reveal no suggestion of a Congressional intent to preempt state tort law. The preemption provision was not mentioned on the floor of the Senate. The preemption provision was debated at length on the floor of the House, but nowhere in the debate is there a suggestion that the preemption provision would affect state tort law.

¶61 Therefore, as pointed out by EPA, rather than reveal an intent to extinguish state common law damage remedies, the legislative history of the 1972 FIFRA amendments is replete with evidence that Congress understood and intended that state damage actions would remain available. Moreover, there is a presumption against preemption of common law remedies. *Medtronic*, 518 U.S. at 485-86, 116 S.Ct. at 2250; *Cipollone*, 505 U.S. at 518, 523, 112 S.Ct. at 2618, 2621. That long standing presumption can only be overcome by evidence of a "clear and manifest" intent of Congress to preempt state law. *See Wisconsin Public Intervenor v. Mortier* (1991), 501 U.S. 597, 610, 111 S.Ct. 2476, 2484, 115 L.Ed.2d 532. In the absence of evidence that Congress intended to alter then existing law, FIFRA should not be interpreted to do so.

¶62 Furthermore, preemption of state tort law would conflict with FIFRA's purposes. The 1972 FIFRA amendments were enacted to address growing public concern with the environmental and public health effects of pesticides such as DDT. The fact that there is no federal private damage remedy, that Congress was aware of state damage remedies,

and that Congress decided to give the states the primary enforcement authority under FIFRA, all strongly imply that Congress did not intend to preempt state common law damage remedies. Given that the 1972 amendments to FIFRA were intended to provide increased public protection against the harms caused by pesticides, it would make no sense to infer that Congress intended to close off all avenues of judicial relief for those injured by pesticides.

¶63 The *Medtronic* plurality adopted similar arguments in interpreting the MDA. Absent a federal private cause of action, preemption of state common law damage actions would effectively bar relief to persons injured by defective medical devices and "have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation. . . ." *Medtronic*, 518 U.S. at 487, 116 S.Ct. at 2251. "It is to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,' and it would take language much plainer than the text of § 360k to convince us that Congress intended that result." *Medtronic*, 518 U.S. at 487, 116 S.Ct. at 2251 (quoting *Silkwood v. Kerr-McGee Corp.* (1984), 464 U.S. 238, 251, 104 S.Ct. 615, 623, 78 L.Ed.2d 443). In the same way, FIFRA's preemptive force should not be interpreted to undermine the statutory purpose to provide increased protection from harmful pesticides.

¶64 We conclude that Congress intended the term "requirements" in § 136v(b) of FIFRA to mean enactments of positive law by legislative or administrative bodies, not state law damage actions. Consequently, we overrule our prior decision in *McAlpine* for holding otherwise.

¶65 Accordingly, we hold that Appellants' claims are not preempted by FIFRA and that the District Court erred in granting summary judgment in favor of DowElanco on that basis.

¶66 Reversed and remanded for further proceedings consistent with this opinion.

s/ James C. Nelson
Justice

s/ J.A. Turnage
Chief Justice

s/ William E. Hunt, Sr.
s/ Jim Regnier
s/ Terry N. Trieweiler
Justices

Hon. Thomas M. McKittrick, District Judge
sitting for Justice W. William Leaphart

s/ Thomas M. McKittrick
District Judge

Appendix A

Justice Karla M. Gray, dissenting.

¶67 I dissent from the Court's opinion. We resolved the dispositive issue in this case, whether failure to warn claims — pleaded in negligence, strict liability and breach of express warranty — are preempted by FIFRA, a scant three years ago in *McAlpine*, holding such claims are preempted to the extent they expressly or implicitly challenge the adequacy of the warnings in a pesticide's label. I would hold that *McAlpine* is controlling and affirm the District Court.

¶68 *Stare decisis*, which means to abide by or adhere to decided cases, is of fundamental and central importance to the rule of law. *State v. Gatts* (1996), 279 Mont. 42, 51, 928 P.2d 114, 119 (citations omitted). It is a " 'fundamental doctrine which reflects our concerns for stability, predictability and equal treatment. . . .' " *Gatts*, 279 Mont. at 51, 928 P.2d at 119 (quoting *Formicove, Inc. v. Burlington Northern, Inc.* (1983), 207 Mont. 189, 194, 673 P.2d 469, 472). The doctrine is meant to keep courts from lightly overruling past decisions, in order to heed the necessity for stability and predictability in the law. *See Gatts*, 279 Mont. at 51, 928 P.2d at 119 (citing *Morayne v. States Marine Lines* (1970), 398 U.S. 375, 403, 90 S.Ct. 1772, 1789, 26 L.Ed.2d 339, 358). At the same time, *stare decisis* is not a mechanical adherence to the latest decision and, of course, court decisions are not sacrosanct. *Gatts*, 279 Mont. at 51, 928 P.2d at 119 (citation omitted). A decision which is manifestly wrong need not be followed. *Gatts*, 279 Mont. at 51, 928 P.2d at 119 (citation omitted). It is my view that, in overruling *McAlpine*, the Court is merely substituting a result it finds preferable to that announced in our well-reasoned *McAlpine*

decision. The Court makes no showing of manifest incorrectness here and, indeed, neither the EPA's *amicus* brief in *Etcheverry* nor the United States Supreme Court's decision in *Medtronic* provides an appropriate basis on which to resolve the present case by overruling *McAlpine*.

¶69 Starting with the U.S. Department of Justice's brief on behalf of EPA in the recent California *Etcheverry* case, I would give it no deference. This is not an internal policy or regulatory statement of the EPA regarding its administration of FIFRA of the type to which courts give deference. It is a brief prepared for litigation, part of the government's litigation strategy. Moreover, as the California Supreme Court observed,

> [e]ven though the question presented in this case has been addressed by nine of the federal circuit courts of appeals, the United States failed to file amicus curiae briefs in any of the cases and permitted those courts to proceed upon a fundamental assumption that it now characterizes as mistaken.

Etcheverry, 993 P.2d at 374. In addition, the matter on which the EPA rests its contention that FIFRA does not preempt failure to warn claims relates to its waiver of review of pesticide efficacy claims. As was the situation in *Etcheverry*, however, the case before us does not relate to pesticide efficacy, that is, whether the pesticide will control the target pest(s). *See Etcheverry*, 993 P.2d at 374. The case before us involves the indoor application of Dursban without ventilation. Thus, as in *Etcheverry*, the EPA's argument is

irrelevant to the case before us. *See Etcheverry*, 993 P.2d at 375. Under these circumstances, the Court's decision to give this johnny-come-lately litigation brief significant weight is a perilously slim basis on which to premise overruling our well-reasoned decision in *McAlpine*.

¶70 Nor do I find *Medtronic* either useful or persuasive here and this no doubt explains why it was not called to our attention in *McAlpine*. As the Court notes several times, the portion of *Medtronic* on which it relies is a four-Justice plurality, clearly not controlling authority even if the MDA and FIFRA contained more similar preemption language. Indeed, it is my view, as it was the view of the California Supreme Court in *Etcheverry*, that *Medtronic* is distinguishable on the basis that Congress gave the Food and Drug Administration a unique role in determining the scope of preemption under the MDA. Congress did not give the EPA an analogous role in implementing FIFRA. *See Etcheverry*, 993 P.2d at 373 (citations omitted).

¶71 I would hold that *Medtronic* does not undermine our conclusion in *McAlpine* that FIFRA preempts state failure to warn claims. In doing so, I would join the overwhelming majority of courts which have examined the question in the wake of *Medtronic*. *See, e.g., Grenier v. Vermont Log Bldgs., Inc.* (1st Cir. 1999), 96 F.3d 559; *Oliver v. Reckitt & Colman, Inc.* (M.D. Fla. 1998), 12 F.Supp.2d 1287; *Hawkins v. Leslie's Poolmart* (D.N.J. 1997), 965 F.Supp. 566; *Kuiper v. American Cyanamid Co.* (E.D. Wis. 1997), 960 F.Supp. 1378; *Koch v. Shell Oil Co.* (D. Kan. 1997), 173 F.R.D. 288; *Etcheverry*, 993 P.2d at 373; *Ackerman v. American Cyanamid Co.* (Iowa 1998), 586 N.W.2d 208; *Ackles v.*

Luttrell (Neb. 1997), 561 N.W.2d 573, *cert. denied*, 522 U.S. 928 (1997); *Didier v. Drexel Chemical Co.* (Wash. App. 1997), 938 P.2d 364; *Lewis v. American Cyanamid Co.* (N.J. 1998), 715 A.2d 967; *Sherman v. Claire Mfg. Co.* (N.Y. App. Div. 1997), 657 N.Y.S.2d 453.

¶72 In my view, no showing has been made that *McAlpine* is "manifestly wrong." *See Gatts*, 279 Mont. at 51, 928 P.2d at 119. Therefore, I would apply *stare decisis* here, reaffirm *McAlpine* and affirm the District Court. I dissent from the Court's failure to do so.

s/ Karla M. Gray
Justice

APPENDIX B — ORDER OF THE MONTANA FIRST JUDICIAL DISTRICT COURT, LEWIS AND CLARK COUNTY ON MOTION FOR SUMMARY JUDGMENT DATED JANUARY 8, 1999

MONTANA FIRST JUDICIAL DISTRICT COURT
LEWIS AND CLARK COUNTY

Cause No. BDV 96-18

LIBBY SLEATH, MARY ANN HAYES, GLENDA TRUESDELL, and MARY OWEN,

Plaintiffs,

v.

WEST MONT HOME HEALTH SERVICES, INC., WEST MONT HOME MANAGEMENT SERVICES, INC., ORKIN EXTERMINATION COMPANY, INC., and EP CO., INC., and ROFAN SERVICES, INC., d/b/a DOW ELANCO,

Defendants.

ORDER ON MOTION FOR SUMMARY JUDGMENT

This matter is before the Court on the motion of Ep Co., Inc., and Rofan Services, Inc., d/b/a Dow Elanco, (hereinafter Dow) for summary judgment. The crux of Plaintiffs' complaint against Dow is that Dow manufactured various formulations of Dursban insecticides that were applied between 1991 and 1994 by Orkin Extermination Company at the office building of West Mont Home Health Services

in Helena, Montana. During that period of time, Plaintiffs worked in the West Mont building.

Plaintiffs, in their second amended complaint, allege three causes of action against Dow. The first is a cause of action for negligence; the second is a breach of warranty; and the final one is a claim of strict liability.

The issue currently before the Court is whether or not Plaintiffs' claims are barred by the Federal Insecticide, Fungicide and Rodenticide Act (hereinafter FIFRA) found at U.S.C. § 136, et seq.

STANDARD OF REVIEW

Summary judgment is proper only when no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Rule 56(c), M.R.Civ.P. It encourages judicial economy through the elimination of unnecessary trial, delay, and expense. *Bonawitz v. Bourke*, 173 Mont. 179, 182, 567 P.2d 32, 33 (1977). However, summary judgment is not to be utilized to deny the parties an opportunity to try their cases before a jury. *Brohman v. State*, 230 Mont. 198, 202, 749 P.2d 67, 70 (1988).

The movant has the initial burden to show that there is a complete absence of any genuine issue of material fact. To satisfy this burden, the movant must make a clear showing as to what the truth is so as to exclude any real doubt as to the existence of any genuine issue of material fact. *Minnie v. City of Roundup*, 257 Mont. 429, 431, 849 P.2d 212, 214 (1993). The burden then shifts to the party opposing the

motion to show that there are genuine issues for trial. *Brinkman and Lenon v. P & D Land Enter.*, 263 Mont. 238, 242, 867 P.2d 1112, 1114 (1994). The party opposing the summary judgment is entitled to have any inferences drawn from the factual record resolved in his or her favor. Rule 56(c), M.R.Civ.P. Rule 56(c) permits the court to render judgment if the pleadings, admissions, and any affidavits filed show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. *Poulsen's, Inc. v. Wood*, 232 Mont. 411, 415, 756 P.2d 1162, 1165 (1988).

DISCUSSION

Four products manufactured by Dow were applied at the West Mont facility; Dursban 4E, Dursban LO, Empire 20 and Dursban granules. Each of these products is registered with the Environmental Protection Agency (EPA) as directed by FIFRA. *See* Robert F. Bischoff Aff.

The labels for the assorted Dursban products contain various instructions on the manner in which the individual products should be used. *See* Bischoff Aff. Exs. A, B and C. All parties agree that the Montana Supreme Court's decision in *McAlpine v. Rhone-Poulenc Ag. Co.*, 285 Mont. 224, 947 P.2d 474 (1997), governs the case at bar. In *McAlpine*, the Montana Supreme Court held:

> Under FIFRA, "a State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C.

> § 136v(b). We determine that, as in the cigarette labeling statute, the phrase "requirement" in 7 U.S.C. § 136v(b) includes state common law damage actions. Therefore, FIFRA preempts state tort claims to the extent they arise from an omission or inclusion in the product's label. Claims alleging a product, manufacturing or design defect, claims alleging negligent design, testing or manufacturing, or claims alleging [a] breach of warranty that do not rely on such an omission or inclusion in the product's label are not preempted.

285 Mont. at 230, 947 P.2d at 477.

The *McAlpine* decision is in accord with what one legal analyst has called a "tsunami of authority." *See, e.g. Louisiana-Pacific Corp. v. Koppers Co.*, 32 Cal. App. 4th 599, 38 Cal. Rptr. 2d 257 (1995); *Taylor AG Industries v. Pure-Gro*, 54 F.3d 555 (9th Cir. 1995); *MacDonald v. Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994); *Worm v. American Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993); *King v. E.I. DuPont de Nemours & Co.*, 996 F.2d 1346 (1st Cir. 1993); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993); *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993) (Papas II); *Arkansas-Platte & Gulf v. Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir. 1993) (Arkansas-Platte II); *Kuiper v. American Cyanamid Co.*, 131 F.3d 656 (1997).

Plaintiffs' admission that their express warranty claim is preempted by FIFRA eases this Court's burden somewhat. *See* Pls' Resp. at 3. However, the Court still must consider

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Plaintiffs' complaint, interrogatory answers and affidavits on file to determine if Plaintiffs' remaining claims are based upon an omission or inclusion in the products' labels.

Prior to addressing these remaining claims, the Court needs to consider two disputes that have arisen between the parties. First, Dow submitted contention interrogatories to Plaintiffs, many of which were answered with reference to the products' labels. Plaintiffs now suggest that the Court should read these interrogatories and omit any reference to the products' labels. Plaintiffs note that these interrogatories were submitted prior to the Montana Supreme Court's decision in *McAlpine* and were in response to Dow's request that Plaintiffs set forth any and all grounds for liability. Contrarily, Dow suggests that the Court's modification to Plaintiffs' answers to the interrogatories not be allowed. However, for purposes of this motion, the Court feels it appropriate to eliminate any specific references to the products' labels that were contained in Plaintiffs' answers to the interrogatories.

Second, Dow contends Dr. Robert K. Simon's supplemental affidavit should be stricken. Dow's contention is that Dr. Simon changed his opinion in his second affidavit, and that this change violates the expert disclosure rule. The Court rejects this argument, holding that Dr. Simon's supplemental affidavit was a necessary response for Plaintiffs to counter the affidavits filed by Dow pursuant to their motion for summary judgment.

At the hearing on the motion for summary judgment, Plaintiffs' attorney indicated that, in essence, his clients'

claim against Dow was a design defect strict liability case. This seemly abandons Plaintiffs' claims against Dow for negligence and breach of implied warranty. However, since nothing is in writing on this particular issue, the Court feels it prudent to address the negligence and implied warranty arguments.

Negligence

Plaintiffs' negligence claim is contained in Count IV of the complaint at paragraph 31. The following allegation is made: "Defendants EP Co., Inc., and Rofan Services, d/b/a DOW ELANCO, and its agents or employees were negligent in failing to provide adequate warning of the known, harmful and inherently dangerous properties of Chlorpyrifos [Dursban] to the public. . . ." If, as Plaintiffs' suggest, Dow was negligent in that it had knowledge of the harmful effects of its products, but failed to provide a warning, this claim must be classified as a failure to warn claim. How, we must ask ourselves, could Dow protect itself from liability for this allegedly negligent activity? Clearly, what Dow would have to do would be to place some warning on its label. As previously noted, a multitude of courts, including the Montana Supreme Court, have held that FIFRA does preempt state law causes of action predicated on a failure to warn. This comes about, primarily, because the failure to warn is an attack on the EPA-approved label for the product.

Breach of Implied Warranty

The interrogatories expanding on Plaintiffs' claim of breach of implied warranty start with Interrogatory No. 2. In Plaintiffs' Answer No. 2c, they aver that Dursban is:

> "not fit to be used in unventilated areas or without limits on the applications . . . . When used according to Defendant DowElanco's instructions, Dursban and/or Chlorpyrifos exposed plaintiff to manufacturing impurities and caused cholinesterase inhibition in plaintiff which may have been avoided by proper warnings and instructions."

The omitted language from Interrogatory No. 2 was the specific mention of the label. However, the remaining information clearly shows that Plaintiffs' complaint deals with the use and application instructions on the product. The labels for all of the Dursban products do have limits on the application and use of the products. Therefore, Plaintiffs are once again, pursuant to their answer to Interrogatory No. 2, challenging the label. Reference can also be made to Interrogatories No. 10 and 12 which refer to "inadequate warnings on its Dursban/Chlorpyrifos products" and "application and use standards." Again, these issues are dealt with on the label. Such being the case, Plaintiffs' claim for breach of implied warranty is, in reality, an attack on the instructions contained on the EPA-approved label.

Dow should be granted summary judgment on both the claim of negligence and breach of implied warranty.

Strict Liability

At oral argument, Plaintiffs suggested that their real claim against Dow was one for a design defect. Strict liability claims, as other common law tort claims, may be preempted by FIFRA. *See McAlpine*, 285 Mont. at 230, 947 P.2d at

477; *Quest Chem. Corp. v. Elam*, 898 S.W.2d 819, 821 (Tex. 1995); *Worm v. America Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993); *Grenier v. Vermont Log Bldgs, Inc.*, 96 F.3d 559 (1st Cir. 1996); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993). However, this area of FIFRA preemption does prove problematic for the Court. The courts have dropped hints as to the type of strict liability claims that could survive FIFRA preemption. For example, a claim that the product was unfit for any use might survive the present motion. *Grenier*, 96 F.3d at 564. Also, if a plaintiff can assert factual grounds for a strict liability claim other than those based on inadequate warnings, FIFRA would not preempt his claim. *See Quest*, 898 S.W.2d at 821.

The *Worm* court noted that "the line between a claim for mislabeling and a claim for a defective product may not always be clear." 5 F.3d at 747. However, the distinction may become less blurred by considering, as one factor, whether it was reasonably foreseeable that the manufacturer, in seeking to avoid liability, would choose to alter the product or the label. *Id.*

The labels on the various products involved here discuss the type of buildings in which the Dursban products may be applied and also discuss the frequency of application of the products. *See* Bischoff Aff. Exs. A, B and C. At issue here is that Plaintiffs' answer to Interrogatory No. 4, which alleges that Dursban causes health problems in humans when used without adequate ventilation and without appropriate limits on applications. Notably, Defendants' labels provide no such instruction. Plaintiffs' answer goes on to state that there are no warnings on the label for the dangers of Dursban and that

repeated use of Dursban in a closed building without adequate ventilation can cause a toxic buildup of the product. Even in omitting the word "label" in the aforementioned answer, it seems clear that the answer to Interrogatory No. 4 is questioning the label instructions for the various Dursban products that are shown on the attachment to Bischoff's affidavit. The label instructions discuss the type of buildings in which Dursban can be applied, and also mention reapplication rates. Thus, at least as far as the interrogatory answer goes, it appears that Plaintiffs' strict liability claim against Dow is, in reality, a label-based claim.

Finally, the Court must review the affidavits of Dr. Simon. Specifically, we must refer to his supplemental affidavit that is attached to Plaintiffs' reply brief in opposition to Dow's motion for summary judgment. In paragraph 3, Dr. Simon states that the design defect making Dursban products unreasonably dangerous to the ultimate consumer in the context of interior workplace application of those products. In paragraph 5 of his supplemental affidavit, Dr. Simon indicates that the known impurities, degradation products and impurities in Dursban cause the products to be unreasonably dangerous, again, in the context of interior workplace application. Again and again in his supplemental affidavit, Dr. Simon refers to the "context of interior workplace application." In his original affidavit, Dr. Simon discusses air flow and ventilation in the West Mont building as being a factor in this problem. *See* Simon Aff., ¶ 8.2. Also in his original affidavit, paragraph 8.5 again talks about the "excessive application of pesticides." All of what Dr. Simon says may well be true. However, underlying his conclusion that these products are unreasonably dangerous is their

application "in the context of interior workplaces" and at the reapplication rate and ventilation rate in those interior areas. These are all topics that are discussed on the various labels of these products. *See* Bischoff Aff. Exs. A, B and C. Plaintiffs must, therefore, be contesting the label directions and warnings related to interior workplace application, ventilation and reapplication of the products. Consequently, their strict liability claim must also be preempted under *McAlpine*.

CONCLUSION

Therefore, based on the above, IT IS HEREBY ORDERED, ADJUDGED AND DECREED that the motion for summary judgment filed by Dow is GRANTED.

DATED this 8 day of Jan. 1999.

s/ Jeffrey M. Sherlock
JEFFREY M. SHERLOCK
District Court Judge

APPENDIX C — FINAL JUDGMENT OF THE MONTANA FIRST JUDICIAL DISTRICT COURT, LEWIS AND CLARK COUNTY PURSUANT TO RULE 54(b) M.R.C.P. DATED FEBRUARY 22, 1999

MONTANA FIRST JUDICIAL DISTRICT COURT
LEWIS AND CLARK COUNTY

Cause No. BDV 96-018

LIBBY SLEATH, MARY ANN HAYES, GLENDA TRUESDELL, and MARY OWEN,

Plaintiffs,

v.

WEST MONT HOME HEALTH SERVICES, WEST MONT HOME MANAGEMENT SERVICES, INC., ORKIN EXTERMINATION COMPANY, and EPCO, INC., and ROFAN SERVICES INC., d/b/a DOWELANCO,

Defendants.

FINAL JUDGMENT PURSUANT TO RULE 54(b) M.R.C.P.

Based upon Plaintiffs and Defendant EPCO, Inc. and Rofan Services, Inc., d/b/a DowElanco (hereinafter DowElanco) motion and the lack of objection by the remaining Defendants and for good cause shown, the Court, pursuant to Rule 54(b), M.R.Civ.P., enters this Final Judgment in this matter, in favor of Defendant

DOWELANCO, and makes the following findings in support of this certification and entry of a Final Judgment:

A. The District Court's Order makes a final ruling as to DowElanco in this proceeding. The claims of Plaintiffs against the other Defendants are not final, indeed none of the other claims are in a status where a definitive ruling will be reached with regard to any of the other non-DowElanco Defendants in the near future and there is no reason to delay entry of a final judgment in favor of DowElanco.

B. The claims against DowElanco are based upon product liability law, and relate to manufacture of DowElanco products, whereas the claims against the remaining Defendants are upon different theories of liability relating to the application of DowElanco products. Thus the claims are distinct and a ruling as to the one class of the Defendants represented by DowElanco will not affect the proceedings against the remaining Defendants. To the contrary, no result of appellate review of the claims against DowElanco will have any effect on the claims or proceedings against remaining Defendants. Finally, there are no claims or counterclaims which could result in a setoff of this judgment.

C. There is no reason to delay the entry of a final judgment in favor of DowElanco and entry of a final judgment will facilitate further handling of the issues in this litigation.

DATED this 22nd day of February, 1999.

s/ JEFFREY M. SHERLOCK
District Judge

APPENDIX D — ORDER OF THE SUPREME COURT OF THE STATE OF MONTANA DENYING PETITION FOR REHEARING DATED AND FILED FEBRUARY 1, 2001

IN THE SUPREME COURT OF THE
STATE OF MONTANA

No. 99-185

LIBBY SLEATH, MARY ANN HAYES, GLENDA TRUESDELL, and MARY OWEN,

Plaintiffs and Appellants,

v.

WEST MONT HOME HEALTH SERVICES, INC., WEST MONT HOME MANAGEMENT SERVICES, INC., ORKIN EXTERMINATION COMPANY, INC., and EP CO., INC., and ROFAN SERVICES, INC., d/b/a DOW ELANCO,

Defendants and Respondents.

ORDER

IT IS ORDERED that the Petition for Rehearing filed with this Court by respondents EP CO, Inc., and Rofan Services, Inc., d/b/a Dow Elanco, is DENIED.

Appendix D

DATED this 1st day of February, 2001.

s/ Karla M. Gray
Chief Justice

s/ James C. Nelson
s/ Jim Regnier
s/ W. William Leaphart
Justices

Justice Terry N. Trieweiler would also deny the petition for rehearing.

APPENDIX E — BRIEF *AMICUS CURIAE* FOR THE UNITED STATES IN *ETCHEVERRY, et al. v. TRI-AG SERVICE, INC., et al.*, SUPREME COURT OF CALIFORNIA, NO. S072524 DATED MARCH, 1999

No. S072524

IN THE SUPREME COURT OF CALIFORNIA

MONIQUE ETCHEVERRY, et al.,

Plaintiffs-Appellants,

v.

TRI-AG SERVICE, INC., BAYER CORP., et al.,

Defendants-Respondents.

ON APPEAL FROM THE COURT OF APPEAL,
THIRD APPELLATE DISTRICT

BRIEF AMICUS CURIAE FOR THE UNITED STATES IN SUPPORT OF PLAINTIFFS-APPELLANTS

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Appendix E

No. S072524

IN THE SUPREME COURT OF CALIFORNIA

MONIQUE ETCHEVERRY, et al.,

Plaintiffs-Appellants,

v.

TRI-AG SERVICE, INC., BAYER CORP., et al.,

Defendants-Respondents.

ON APPEAL FROM THE COURT OF APPEAL,
THIRD APPELLATE DISTRICT

BRIEF AMICUS CURIAE FOR THE UNITED STATES IN SUPPORT OF PLAINTIFFS-APPELLANTS

INTEREST OF THE UNITED STATES

This appeal addresses the preemptive effect of 7 U.S.C. 136v, the provision of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that establishes the authority of state governments to regulate pesticides. The preemptive effect of FIFRA implicates at least two important federal interests. First, the United States has a general interest in the preemptive force of federal statutes and in properly delineating the regulatory authorities of the state and federal governments. Pursuant to that interest, the United States seeks to ensure that federal law does not deprive individuals

of otherwise available state-law remedies unless Congress clearly manifested an intent to do so. Second, the United States Environmental Protection Agency (EPA) is the primary agency charged by Congress with the administration of FIFRA. Because FIFRA establishes a broad program of joint federal-state regulation, EPA's authority over pesticides is necessarily affected by the scope of state authority. Believing that state tort law would be available as a check on inadequate or false manufacturer statements regarding pesticide efficacy, EPA approves pesticide labels without evaluating those claims. Accordingly, the United States has institutional and programmatic interests in the resolution of this appeal.

FIFRA'S STATUTORY AND REGULATORY FRAMEWORK

First enacted in 1947, P.L. 80-103, 61 Stat. 163, FIFRA established a federal program for the regulation of pesticides. The 1947 Act required the registration of pesticides with the Secretary of Agriculture, the display of poison warnings on the labels of highly toxic pesticides, and the inclusion of other warning statements to prevent injury to people, animals, and plants. In 1949, pursuant to his authority under FIFRA, the Secretary issued substantial pesticide labeling requirements. See 7 C.F.R. Part 162 (1949). In 1970, authority for pesticide regulation was transferred to the newly-created EPA,[1] which administered the pesticide labeling requirements imposed by the Department of Agriculture. See 7 C.F.R. Part 2762 (1971).

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1. See Reorganization Plan No. 3 of 1970, section 2(8)(i), 5 U.S.C. Appendix at 610 (1970).

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In 1972, largely in response to public concerns over the pesticide DDT,[2] Congress enacted sweeping amendments to FIFRA. Those amendments establish that the primary purpose of federal pesticide regulation is the protection of human health and the environment from the risks posed by pesticides.[3] While FIFRA had previously regulated pesticides primarily through labeling requirements, the 1972 amendments established federal regulation of pesticide use, an area previously regulated exclusively by states.[4]

As amended by the 1972 amendments, FIFRA establishes a broad program of federal-state cooperation in

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2. See, e.g., *Burke v. Dow Chemical Co.*, 797 F. Supp. 1128, 1134 (E.D.N.Y. 1992) ("The statute was completely overhauled in 1972 * * * in light of concerns over the health risks of DDT and other chemical pesticides."); 118 Cong. Rec. 32,259 (statement of Sen. Neson) (Sept. 26, 1972); *id.* at 32,262 (statement of Sen. Tunney); 118 Cong. Rec. 40,038 (statement of Rep. Dow) (Nov. 9, 1971); S. Rep. No. 970, 92d Cong., 2d Sess. 9 (1972); Federal Environmental Pesticide Control Act: Hearings Before the Subcomm. on Ag. Research of the Sen. Comm. on Ag. and Forestry, 92d Cong., 1st Sess. 141 (statement of Sen. Nelson) (1971).

3. See *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 601 (1991) ("In 1972, growing environmental and safety concerns led Congress to undertake a comprehensive revision of FIFRA."); S. Rep. No. 838, 92d Cong., 2d Sess. 3 (1972) ("This bill provides for the more complete regulation of pesticides in order to provide for the protection of man and his environment and the enhancement of the beauty of the world around him.").

4. See *Mortier*, 501 U.S. at 601; H. Rep. No. 511, 92d Cong., 1st Sess. 4 (1972).

regulating pesticides. Under this program, EPA registers pesticides for particular uses and approves pesticides labels. 7 U.S.C. 136a(5). FIFRA requires that, in registering pesticides and approving their labels, EPA must determine (a) that the pesticide's "composition is such as to warrant the proposed claims for it," (b) that the labeling and other materials "comply with the requirements" of FIFRA, (c) that the pesticide "will perform its intended function without unreasonable adverse effects on the environment," and (d) that "when used in accordance with widespread and commonly recognized practice" the pesticide will not have unreasonable adverse effects on the environment. *Ibid.* Pursuant to a 1978 amendment, EPA does not evaluate pesticide label claims regarding efficacy or otherwise regulate efficacy in approving pesticide labels. *Ibid.*

Under FIFRA, state governments have a substantial role in regulating pesticides. As the Supreme Court stated, FIFRA "leaves ample room for States and localities to supplement federal efforts." *Mortier*, 501 U.S. at 613. FIFRA gives states the lead role in enforcing pesticide use restrictions. 7 U.S.C. 136w-1; see also 7 U.S.C. 136u.

States further retain broad authority to regulate the sale and use of pesticides:

> (a) **In general.** A state may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

> (b) **Uniformity.** Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.
>
> (c) **Additional uses.** (1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator.

7 U.S.C. 136(v). Under subsection (a), states may regulate pesticide sales or use more strictly than the federal government. Under subsection (c) and accompanying regulations, states may register pesticides for local uses in addition to those approved by EPA and may impose supplemental labeling requirements regarding those additional uses. See 40 C.F.R. 162.153(e). Under subsection (b), which is at issue in this appeal, states may not impose pesticide labeling "requirements" that are "in addition to or different from" requirements imposed under FIFRA.

SUMMARY OF ARGUMENT

The majority of courts that have examined the question presented by this case have concluded that FIFRA preempts all state-law failure to warn actions and all other state-law tort actions that implicate federally approved pesticide labels. The United States was not a party in any of those actions

and has not previously expressed an opinion in court on whether FIFRA preempts state-law damages actions.[5] In June 1996, recognizing that the decisions holding that FIFRA preempts state tort law reflect a widespread misunderstanding of EPA's role in regulating pesticides, EPA issued Pesticide Regulation Notice 96-4 (PR 96-4), which details the process for registering pesticides under FIFRA. See Addendum. As PR 96-4 explains, EPA's approval of a pesticide does not involve evaluation of pesticide label statements regarding the product's efficacy. EPA waived review of efficacy statements pursuant to express authorization by Congress, 7 U.S.C. 136a(c)(5), and it did so based on its conclusion that state tort law provides an effective means of ensuring the adequacy of statements regarding efficacy. Having published PR 96-4, the United States submits this brief to more fully inform the Court of its views on the preemptive force of FIFRA.

FIFRA does not preempt state-law actions for damages. Section 136v(b) prohibits states from imposing labeling "requirements" in addition to, or different from, those imposed under FIFRA. While the term "requirements" may encompass common law duties in some contexts, the text, legislative history, and purposes of FIFRA demonstrate that Congress had no intent that the use of the term "requirements" in section 136v(b) would extinguish state law

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5. The United States' brief in *Mortier* stated that "Congress clearly preempted all but federal regulation of labels." Brief for the United States as Amicus Curiae, *Wisconsin Public Intervenor v. Mortier*, No. 89-1950 (Oct. Term 1990). The brief did not, however, take any position on whether state damages actions impose "requirements" under section 136v(b).

damages actions. When section 136v(b) was enacted in 1972, state law actions against pesticide manufacturers for failure to warn were a commonplace and uncontroversial feature of the legal landscape. No evidence from the text or legislative history of FIFRA suggests that Congress had any intent to extinguish those actions or that Congress even considered doing so. Indeed, Congress amended FIFRA in 1972 out of increasing concern for the human health and the environmental effects of pesticides such as DDT. Given that FIFRA establishes no private damages remedy for those injured by pesticides, it would be astonishing that, without any discussion, Congress could have intended to deprive injured persons of all means of relief.

Even if FIFRA could be read to preempt some state damages actions, it cannot be read to preempt tort actions addressing the efficacy of pesticides. Pursuant to express congressional authorization, EPA has waived review of pesticide label statements regarding the efficacy of pesticides. Congress encouraged EPA to waive efficacy review in order to streamline the process for federal approval of pesticides. In authorizing the waiver, Congress anticipated that the states would fill the regulatory gap. No evidence suggests that Congress intended to leave the subject of pesticide efficacy unregulated by both the state and federal governments. A finding that FIFRA preempts state damages actions for efficacy-related claims would have a consequence unintended by Congress: in the area of pesticide efficacy, there would be not only an absence of federal labeling regulation but also preemption of state damages claims.

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Even if FIFRA could be read to preempt state damages actions challenging the claims on pesticide labels regarding efficacy, it does not preempt damages claims challenging off-label statements. FIFRA only prohibits states from imposing "labeling" requirements; damages actions alleging harm from pesticide advertising, or from oral statements of pesticide manufacturers, do not impose any "labeling" requirements. The Supreme Court has repeatedly instructed that express preemption provisions like section 136v(b) must be interpreted narrowly and should not be interpreted to preempt traditional areas of state regulation unless Congress manifested a clear intent to effect such preemption. Here, Congress has only preempted state labeling requirements; it has not expressed any intent to regulate pesticide manufacturer statements that do not appear on the label.

The courts that have concluded that FIFRA preempts state-law damages actions have done so, we respectfully submit, without fully examining the text, regulatory background, legislative history, and purposes of FIFRA. Many important factors not considered by the courts persuade the United States that FIFRA was not intended to preempt state-law actions for damages: (1) that Congress did not establish a federal damages remedy to replace state damages remedies and that preemption would thus leave individuals injured by pesticides largely, or entirely, without a remedy; (2) that Congress drafted section 136v(b) against the existing regulatory background of FIFRA, which, since 1949, has included a well-developed body of federal pesticide labeling requirements, suggesting that Congress only intended to prevent states from imposing similar labeling requirements; (3) that Congress drafted section 136v(b) against the existing

common law background, which, since 1884, has authorized the imposition of damages for false or inadequate statements regarding pesticides; (4) that the voluminous legislative history of section 136v(b) overwhelmingly demonstrates that Congress was exclusively concerned with preventing conflicting state regulations of pesticide labeling by state administrative agencies and that no member of Congress ever mentioned an intent to preempt state damages actions; (5) that Congress gave EPA authority to waive review of pesticide efficacy based on its expectation that states would fill the regulatory gap; and (6) that, pursuant to congressional authorization, EPA has waived regulatory review of pesticide label claims regarding product efficacy when it approves pesticide labels. Because no court has examined those factors, the United States believes that its views will assist this Court in determining FIFRA's preemptive force.

ARGUMENT

I. FIFRA DOES NOT PREEMPT STATE COMMON LAW DAMAGES ACTIONS

The Supreme Court has repeatedly emphasized that there is a "presumption against the pre-emption of state police power," *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992), and that the determination of whether federal law preempts traditional areas of state authority must therefore "start with the assumption that the historic police powers of the States [are] not to be superseded by * * * Federal Act unless that [is] the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). The presumption against preemption derives from core principles of federalism, which guarantee states the freedom

to regulate as independent sovereigns within their traditional spheres. *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996). Moreover, in every preemption case, "[t]he purpose of Congress is the ultimate touchstone." *Ibid.* (quoting *Retail Clerks v. Schemerhorn*, 375 U.S. 96, 103 (1963)).

The text and history of FIFRA reveal no "clear and manifest" congressional intent to extinguish state-law actions for damages.[6] On the contrary, the text and history demonstrate that Congress intended only to prevent state administrative bodies from issuing labeling regulations that conflicted with federal requirements. No evidence suggests that Congress ever intended to deprive injured persons of state-law damages remedies. Moreover, given that FIFRA establishes no federal damages remedy, preemption of state tort law would strongly conflict with the central purpose of the 1972 FIFRA amendments — providing *increased* public protection against pesticides.

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6. While this case addresses pesticide manufacturers' liability for failure to warn, other courts have held that FIFRA preempts *any* claim that challenges the adequacy of a pesticide label, including implied breach of warranty, see, e.g., *Worm v. American Cyanimid Co.*, 5 F.3d 744, 748 (4th Cir. 1993), *Papas v. Upjohn Co.*, 985 F.2d 516, 518 (11th Cir. 1993); express breach of warranty, see, e.g., *Grenier v. Vermont Log Buildings, Inc.*, 96 F.3d 559, 563-565 (1st Cir. 1996); *Welchert v. American Cyanamid Inc.*, 59 F.3d 69, 71-73 (8th Cir. 1995); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995); strict liability, see, e.g., *Papas*, 985 F.2d at 518, *Arkansas-Platte & Gulf v. Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir. 1993); negligence, see, e.g., *Papas*, 985 F.2d at 518; *Arkansas-Platte*, 981 F.2d 1177; design defect, see, e.g., *Grenier*, 96 F.3d at 563-565, *Worm*, 5 F.3d at 748; and negligent testing, see, e.g., *Taylor*, 54 F.3d at 563; *Worm*, 5 F.3d at 748.

Appendix E

A. As the Supreme Court's Decisions in *Cipollone* and *Medtronic* Demonstrate, FIFRA's Preemption Provision Must Be Read in Its Statutory Context

FIFRA prohibits states from imposing "requirements" on pesticide labels in addition to those imposed under the Act. 7 U.S.C. 136v(b). The central issue here is whether the term "requirements" under section 136v(b) includes state common law damages actions. The United States does not dispute the contention that in some contexts the word "requirements" may encompass obligations imposed through common law damages actions. The text, legislative history, and purposes of FIFRA demonstrate, however, that, as it is used in section 136v(b), the term "requirements" means direct commands imposed by law regarding the contents of labels. In this context, the term "requirements" does not include state damages actions because such actions do not mandate any changes in labeling.

The Supreme Court has long recognized that the terms of federal statutes must not be read in isolation but must be understood in their statutory context.[7] In *Cipollone v. Liggett Group. Inc.*, 505 U.S. 504 (1992), and *Medtronic v. Lohr*, 518 U.S. 470 (1996), the Supreme Court interpreted two express preemption provisions that prohibited states from imposing certain types of "requirements." Examining the

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7. See *United States Nat. Bank of Ore. v. Independent Ins. Agents of America, Inc.*, 508 U.S. 439, 455 (1993) (quoting *United States v. Heirs of Boisdore*, 49 U.S. (8 How.) 113, 122 (1849)) (" 'In expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.' ").

different statutory contexts, the Court reached different conclusions as to whether Congress intended the term "requirements" to encompass state damages actions.

In *Cipollone*, the Court found that the Public Health Cigarette Smoking Act of 1969 (the 1969 Cigarette Act) preempted state common law damages actions for inadequate labeling. The 1969 Cigarette Act barred states from imposing any " requirement or prohibition based on smoking and health * * * with respect to the advertising or promotion of any cigarettes." That provision superseded the preemption provision of the 1965 Federal Cigarette Labeling and Advertising Act (the 1965 Cigarette Act), which barred states from mandating that any "statement" appear on cigarette advertising. The Court held that the 1965 Cigarette Act's bar on promotional "statements" did not preempt state damages actions. 505 U.S. at 518-520. A four-Justice plurality concluded that the 1969 Cigarette Act, which expanded the bar to include promotional "requirements," did preempt certain obligations imposed by state common law. In reaching its conclusion, the plurality credited the broadening of the statutory language with expressing a congressional intent to expand the preemptive force of federal cigarette laws.

In contrast, in *Medtronic*, the Court found that the Medical Devices Amendments of 1976 (MDA) did not preempt state common law damages actions. Like the preemption provision of the 1969 Cigarette Act, the MDA prohibited states from imposing "requirements" on medical devices in addition to federal requirements imposed under the Act. 21 U.S.C. 360k(a). The Court ruled, however, that

the MDA did not preempt state common law damages actions. A four-Justice plurality found that distinct features of the MDA mandated the conclusion that Congress intended only to preempt states from imposing positive law "requirements" on medical devices in the form of regulations or laws and did not intend to preempt common law damage actions.[8] 518 U.S. at 488-89.[9]

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8. The *Medtronic* plurality found five key differences in the statutory schemes of the 1969 Cigarette Act and the MDA that mandated the conclusion that Congress did not intend the word "requirements" to mean the same thing in both statutes. First, the preemption of state authority resulting from the 1969 Cigarette Act prevented only "a limited set of state requirements" — requirements imposed on advertising regarding the health effects of cigarettes, while preemption of common law actions as a result of the MDA would extinguish all state law design defect claims regarding all medical devices. *Id.* at 488. Second, the MDA provided no private damages action that would replace state common law actions. Third, the MDA's preemption provision, unlike the 1969 Cigarette Act's, expressed congressional concern "with the problem of specific, conflicting State statutes and regulations rather than the general duties enforced by common-law actions." *Id.* at 489. Fourth, unlike the 1969 Cigarette Act, the MDA uses the word "requirements" in numerous provisions, and each use clearly refers only to statutory and regulatory law, not common law. Fifth, the legislative history of the MDA reveals no reference in the hearings, committee reports, or debates that suggests a congressional intent to preempt all common-law remedies.

9. Agreeing that the meaning of the term "requirements" depends on the statutory context, Justice Breyer concurred on the ground that, as used in the MDA, the word "requirements" is ambiguous and therefore the Food and Drug Administration, which administers the MDA, is entitled to deference for its view that state law is not preempted. 518 U.S. at 503-508.

Cipollone and *Medtronic* may appear to be in some tension but in fact teach the same lesson: that the term "requirements" must be interpreted in its statutory context. As the Supreme Court has said, "Only mischief can result if [the same words appearing in different statutes] are given one meaning regardless of the statutory context." *Lee v. Madigan*, 358 U.S. 228, 231 (1959). An examination of the text, legislative history, and purposes of the 1972 FIFRA amendments reveals that, by preempting state labeling "requirements," Congress did not intend to preempt traditional state damages actions against pesticide manufacturers for failure to warn.

B. The Text of FIFRA Demonstrates that Congress Did Not Intend to Preempt Common Law Actions

FIFRA's text demonstrates that Congress had no intent to extinguish damages remedies under state common law. First, in section 136v, Congress used the term "requirements" to mean "regulation," a term connoting positive commands of law, not court orders to pay damages for the harms caused by pesticides. Second, the term "requirements" appears in FIFRA 75 times, and each time refers to direct commands of law, which state damages actions do not impose. Third, subsections 136v(a) and (c) demonstrate that Congress intended to authorize states to take actions that may *indirectly* prompt pesticide manufacturers to change their labels; *indirect* pressure on pesticide manufacturers to change their labels, which may result from liability in damages actions, cannot be characterized as labeling "requirements."

Appendix E

1. Under section 136v, the term "requirements" refers to state commands regarding labeling content.

Section 136v(b)'s bar on state-imposed labeling "requirements" must be interpreted in its context as a subsection of section 136v, the provision of the 1972 amendments entitled "Authority of States." Without section 136v, state regulation of pesticide use might have been eliminated by the 1972 amendments. Prior to 1972, the federal government regulated pesticides primarily through a registration process requiring federal approval of pesticide labels. S. Rep. No. 838, 92d Cong., 2d Sess. 3 (1972). The 1972 amendments expanded federal regulation to include pesticide use, an area previously regulated exclusively by states. *Ibid.*

Section 136v clarifies the continuing role of state governments in pesticide regulation, authorizing states to regulate pesticides more stringently than EPA. Section 136v(a) thus provides that "[a] State may regulate" the sales or use of pesticides as long as the state "regulation" does not permit a sale or use prohibited by FIFRA. Section 136v(b) forbids "[s]uch state" from regulating labeling by imposing labeling "requirements" in addition to or different from those required under FIFRA. The plainest reading of the two subsections is that a state may "regulate" pesticide sales or use, but in doing so may not impose labeling "requirements." In other words, section 136v(b)'s prohibition on state labeling "requirements" represents an exception to section 136v(a)'s general grant of state authority to "regulate" pesticide sales and use. Congress could only have intended that the term

"requirements" in section 136v(b) refers to a subset of state "regulation" in section 136v(a). As a majority of the Court held in *Cipollone*, "the term 'regulation' most naturally refers to positive enactments by those bodies, not to common-law damages actions." 505 U.S. at 519. Section 136v clearly preempts state labeling commands, but suggests no congressional intent to preempt state damages actions.

2. FIFRA's other references to "requirements" all refer to direct commands imposed by law, not the indirect pressure resulting from tort liability.

The *Medtronic* plurality interpreted the term "requirements" in the MDA's preemption provision by examining its usages throughout the MDA. In doing so, the plurality adhered to "the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning." *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990) (internal quotation marks omitted). Throughout FIFRA, the term "requirements" refers exclusively to positive commands of law. Accordingly, the term "requirements" should be given the same reading in section 136v(b).

The term "requirements" appears seventy-five times in FIFRA, and each time refers only to positive law requirements.[10]

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10. See 7 U.S.C. 136(q)(1)(F) (a pesticide is "misbranded" if its label does not contain "requirements" imposed under FIFRA); 7 U.S.C. 136(q)(1)(G) (same); 7 U.S.C. 136a(b)(2) (unregistered pesticides may be transferred in accordance with "the requirements

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of an experimental use permit"); 7 U.S.C. 136a(c)(2)(A) (EPA may establish "standards for data requirements for the registration of pesticides with respect to minor uses"); 7 U.S.C. 136a(c)(2)(B)(iv) (suspended pesticide shall be reinstated upon a showing that the registrant "has complied fully with the requirements that served as a basis for the notice of intent to suspend"); 7 U.S.C. 136a(c)(2)(B)(viii)(I)(A) ("data requirements" imposed by federal and state authorities); 7 U.S.C. 136a(c)(2)(B)(viii)(III) ("the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements."); 7 U.S.C. 136a(c)(2)(E) (criteria under which EPA "may waive otherwise applicable data requirements"); 7 U.S.C. 136a(c)(5)(B) (EPA shall register pesticides if, inter alia, "its labeling and other material required to be submitted comply with the requirements of this subchapter"); 7 U.S.C. 136a(c)(6) (denial of registration for failing to satisfy FIFRA's "requirements"); 7 U.S.C. 136a(c)(9)(B) (labeling "requirements"); 7 U.S.C. 136a(g)(1)(A) (EPA must follow "the procedures and substantive requirements of section 136d"); 7 U.S.C. 136a(h) (imposing "[r]egistration requirements for antimicrobial pesticides"); 7 U.S.C. 136a(h)(3)(A)(ii) (establishing "requirements" for proposed regulations addressing antimicrobial pesticides); 7 U.S.C. 136a(h)(3)(B)(iii) (establishing "requirements" for final regulations); 7 U.S.C. 136a(h)(3)(C); 7 U.S.C. 136a(h)(4)(B) (data requirements); 7 U.S.C. 136a-1(a)(1) (data requirements); 7 U.S.C. 136a-1(a)(2) ("requirements of section 136a(c)(5)"); 7 U.S.C. 136a-1(b)(4) (data requirements); 7 U.S.C. 136a-1(c)(1)(C) (data requirements); 7 U.S.C. 136a-1(e)(1)(A) ("requirements of section 136a"); 7 U.S.C. 136a-1(e)(1)(B) (same); 7 U.S.C. 136a-1(e)(1)(D) (same); 7 U.S.C. 136a-1(e)(4)(A)(iv) (same); 7 U.S.C. 136a-1(f)(1) (data requirements); 7 U.S.C. 136a-1(f)(1)(B) (same); 7 U.S.C. 136a-1(g)(2)(C) ("requirements of section 136a(c)(5)"); 7 U.S.C. 136a-1(g)(2)(E)(ii) (requirements of the Federal Food, Drug, and Cosmetic Act); 7 U.S.C. 136a-1(j) (exemption from "the requirements

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FIFRA establishes "data requirements,"[11] "time

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of subsections (d), (e), (f), and (i)"); 7 U.S.C. 136d(b)(2) (time requirements); 7 U.S.C. 136d(f)(3)(D) ("data and other requirements"); 7 U.S.C. 136d(f)(4) (data requirements); 7 U.S.C. 136f(a) (recordkeeping requirements); 7 U.S.C. 136g(c)(1) (civil and criminal proceedings for failing to comply with requirements of subchapter); 7 U.S.C. 136i(a)(1) (requirements on state certification of pest applicators); 7 U.S.C. 136i-1(a) recordkeeping requirements for certified applicators); 7 U.S.C. 136i-1(e) (requirements of this section do not affect state or federal laws); 7 U.S.C. 136j(b)(1) (exemption from penalties for certain persons who comply with requirements of this subchapter); 7 U.S.C. 136k(b)(3) (seizure of pesticides that cause harm but comply with requirements of this subchapter); 7 U.S.C. 136m(a)(2)(A) (indemnity unless registrant should have known pesticide did not meet requirements for registration); 7 U.S.C. 136q(a)(1) (data requirements); 7 U.S.C. 136q(a)(1)(B) (label requirements for transportation); 7 U.S.C. 136q(a)(2)(A) (EPA authority to issue regulatory requirements; 7 U.S.C. 136q(a)(2)(B) (same); 7 U.S.C. 136q(a)(2)(C) (same); 7 U.S.C. 136q(a)(3)(A) (same); 7 U.S.C. 136q(a)(3)(B) (same); 7 U.S.C. 136q(a)(3)(C) (same); 7 U.S.C. 136q(f)(1)(B)(iv) (requirements under Solid Waste Disposal Act); 7 U.S.C. 136q(f)(1)(C) (exemptions from requirements of this subchapter); 7 U.S.C. 136q(f)(3) (requirements of Solid Waste Disposal Act); 7 U.S.C. 136q(h) (same); 7 U.S.C. 136v(b) (state labeling requirements); 7 U.S.C. 136w(a)(2)(C) (time requirements) 7 U.S.C. 136w(b) (exemption from requirements of this subchapter); 7 U.S.C. 136w(d) (time requirements); 7 U.S.C. 136w-1(b) (requirements of section 136i); 7 U.S.C. 136w-2(a) (referral to state officials for investigation consistent with requirements of this subchapter); 7 U.S.C. 136w-5 (state minimum requirements for training applicators).

11. See, e.g., 7 U.S.C. 136a-1(a)(1); 7 U.S.C. 136a-1(b)(4); 7 U.S.C. 136a-1(f)(1); 7 U.S.C. 136d(f)(4); 7 U.S.C. 136q(a)(1).

requirements,"[12] "registration requirements,"[13] and "recordkeeping requirements."[14] FIFRA refers to "requirements" imposed under other federal and state laws.[15] All of these references to "requirements" clearly encompass commands imposed by statute or regulation.

FIFRA's many usages of the term "requirements," including section 136v, demonstrate that Congress understood "requirements" to be a subset of "regulations." For example, EPA "may by *regulation* * * * issue requirements" regarding pesticide storage and transportation.[16] EPA may "by *regulation* * * * issue *requirements*" for disposing of certain pesticides,[17] pesticide containers,[18] and pesticide container rinsing agents.[19]

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12. See, e.g., 7 U.S.C. 136d(b)(2); 7 U.S.C. 136w(a)(2)(C); 7 U.S.C. 136w(d)(1).

13. See, e.g., 7 U.S.C. 136a(h).

14. See, e.g., 7 U.S.C. 136f(a); 7 U.S.C. 136i-1(a).

15. See, e.g., 7 U.S.C. 136a-1(g)(2)(E); 7 U.S.C. 136q(f)(1)(B)(iv); 7 U.S.C. 136i-1(e); 7 U.S.C. 136q(h); 7 U.S.C. 136w-5.

16. 7 U.S.C. 136q(a)(2)(A) (emphasis added). See also 7 U.S.C. 136q(a)(3)(A).

17. 7 U.S.C. 136q(a)(2)(B), (C) (emphasis added).

18. 7 U.S.C. 136q(a)(3)(B).

19. 7 U.S.C. 136q(a)(3)(C).

Furthermore, each reference to *labeling* "requirements" refers to statutory or regulatory commands. For example, FIFRA mandates that EPA register a pesticide only if its labeling complies with the labeling "*requirements*" imposed under FIFRA.[20] FIFRA defines a pesticide to be "misbranded" if its label does not meet the various "*requirements*" imposed under FIFRA.[21] Since FIFRA refers exclusively to labeling "requirements" imposed by regulation, section 136v(b) cannot be read to encompass voluntary labeling changes resulting from a state damages action.

As the *Medtronic* plurality concluded with respect to the uses of the term "requirements" in the MDA, the uses of the term "requirements" throughout FIFRA demonstrate that "its focus is * * * positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries." 518 U.S. at 489. Specifically, FIFRA's usage of the term "requirements" demonstrates (1) that Congress used the term "requirements" to denote a subset of "regulations," a term connoting positive commands of law, and (2) that Congress understood labeling "requirements" to refer to labeling commands imposed by statute and regulation.

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20. 7 U.S.C. 136a(c)(5).

21. 7 U.S.C. 136(q)(1)(F),(G). See also, e.g., 7 U.S.C. 136a(c)(9)(B) (entitled "Requirements," establishes that pesticide labels must not "conflict with or detract from any statement required by law or the Administrator as a condition of registration") 7 U.S.C. 136a(c)(9)(B); 7 U.S.C. 136q(a)(1)(B) (the Administrator may impose regulations mandating that "the labeling of a pesticide contain requirements and procedures for the transportation, storage, and disposal of the pesticide").

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3. Section 136v addresses state *commands* regarding labeling, not state actions that *indirectly* pressure pesticide manufacturers to change their labels.

A state court award of damages for failure to warn does not mandate any change in labeling. Rather, it merely requires that a pesticide manufacturer pay money to an injured person. While a damages award may prompt a pesticide manufacturer to seek EPA approval for a change in labeling, it does not directly command such a change.[22] In several provisions of FIFRA, Congress authorized states to apply *indirect* pressure on pesticide manufacturers to change their labels. For instance, pursuant to section 136v(a), a state may prohibit pesticide use or restrict Pesticide sales for any reason, including the adequacy of warnings. Pesticide use or sales restrictions may pressure pesticide manufacturers to seek EPA approval to alter a pesticide label. Alternatively, a pesticide manufacturer may request EPA approval to change a pesticide label in order to promote additional pesticide uses approved by states under section 136v(c) that have not been approved by EPA pursuant to section 136a(c)(5).[23] Damages awards, like use or sale prohibitions,

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22. In contrast, an injunction imposed against a manufacturer to change its label would represent a state-mandated labeling requirement and would therefore be preempted.

23. Pursuant to their authority under section 136v(c), states may *directly* impose supplemental labeling requirements regarding state-approved local uses. 40 C.F.R. 162.153(e). If the pesticide manufacturer seeks to alter the label nationally, however, it must obtain EPA approval.

and state-approved additional uses, may *indirectly* pressure pesticide manufacturers to change their labels. But such indirect pressure cannot reasonably be characterized as imposing labeling requirements.

Moreover, indirect pressure to change a pesticide label does not frustrate Congress's purpose of establishing nationally uniform pesticide labels. EPA approves only one label per pesticide. In approving a labeling change, EPA substitutes a new nationally uniform label. This process is the same whether the labeling change is prompted by state damages liability or state regulation authorized by FIFRA.

The concern that state damages awards would impose requirements that conflict with EPA's determinations is unfounded. Damages awards do not impose labeling "requirements" as that term is used in FIFRA. Furthermore, in state-law damages actions, EPA's evaluation and approval of pesticide label statements may be *evidence* of the adequacy of the label or a pesticide manufacturer's conduct. For example, where a pesticide manufacturer shows that it requested EPA approval of a particular label statement and EPA rejected the request, tort law ordinarily will preclude the imposition of liability for failing to include the statement. See Restatement (Second) of Torts §§ 286-288C.[24] Because pesticide manufacturers remain free to seek alterations of their labels, however, EPA approval of a pesticide label should not completely shield a pesticide manufacturer from state law liability.

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24. In addition, a state judgment imposing liability for failing to include a label statement that EPA rejected may result in an *actual* conflict between state and federal law and may therefore be precluded as a result of *implied* preemption analysis.

Appendix E

C. The History of FIFRA Demonstrates No Congressional Intent to Extinguish Actions for Damages

When section 136v(b) was enacted in 1972, common law actions against pesticide manufacturers for failure to warn were widely available and had been held not to conflict with federal labeling requirements. The legislative history of the 1972 FIFRA amendments include no suggestion of an intent to extinguish common law damages actions.[25] Indeed, the legislative history overwhelmingly demonstrates that Congress enacted section 136v(b) to preclude state administrative bodies from imposing commands on the content of pesticide labels, not to alter existing tort remedies.

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25. In *Medtronic* the plurality refused to accept that Congress intended to preempt common-law damages actions where the legislative history was devoid of such intent:

> There is, to the best of our knowledge, nothing in the hearings, the committee reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices. If Congress intended such a result, its failure even to hint at it is spectacularly odd.

Medtronic, 518 U.S. at 491. That Congress could intend FIFRA preemptive force to be so sweeping is no less incredible, given the total absence of legislative history evincing such intent.

Appendix E

1. When section 136v(b) was enacted, common law actions against pesticide manufacturers for failure to warn were a well-recognized and uncontroversial feature of the legal landscape.

Section 136v cannot be understood without an appreciation for the common law in 1972. A court must "presume that Congress is knowledgeable about existing law pertinent to the legislation it enacts." *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988). A court should interpret a statute to alter existing law only if Congress intended that result.[26] Because common law actions for failure to warn about pesticides were widely available in 1972 and no evidence hints that Congress intended to eliminate those actions, a court should not read section 136v to do so.[27]

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26. See *United States v. Texas*, 507 U.S. 529, 540-541 (1993) (Stevens, J., dissenting) ("We presume that Congress understands the legal terrain in which it operates, * * * and we therefore expect Congress to state clearly any intent to reshape that terrain."); cf. *Oubre v. Entergy Operations, Inc.*, 118 S. Ct. 838, 845-846 (1998) ("[C]ommon-law doctrines 'ought not to be deemed repealed, unless the language of a statute be clear and explicit for this purpose.' ") (quoting *Fairfax's Devisee v. Hunter's Lessee*, 11 U.S. (7 Cranch) 603, 623 (1812)).

27. The widespread availability of failure to warn actions against pesticide manufacturers at the time section 136v was enacted contrasts sharply with the unavailability of damages actions against cigarette manufacturers at the time of the enactment of the federal cigarette labeling statutes at issue in *Cipollone*. See Robert L. Rabin, "A Sociolegal History of the Tobacco Tort Litigation," 44 Stan. L. Rev. 853 (1992).

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Common law actions for inadequate, misleading, or false representations regarding pesticides were available at least as early as 1884.[28] In the first part of this century, dozens of reported decisions recognized the availability of actions for false or inadequate representations regarding pesticides, including actions based on pesticide labels.[29] After FIFRA was enacted in 1947, the federal government issued substantial labeling regulations,[30] but state and federal courts

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28. See *Jones v. George*, 61 Tex. 345 (1884) (action against the seller of "Royall's Patent or Receipt for Killing Worms," which was represented as effective against cotton worms but which failed to control the worms).

29. See, e.g., *White v. National Bank of Commerce*, 278 P. 915 (Cal. D. Ct. App. 1929) (crop damage action against seller of "Volck Concentrate," falsely represented to control pests without harming citrus trees); *West Disinfecting Co. v. Plummer*, 44 App. D.C. 345 (D.C. Cir. 1916) (personal injury action against maker of "Kil-Bug" for allegedly inadequate label); *Ebers v. General Chem. Co.*, 17 N.W.2d 176 (Mich. 1945) (action for crop damage caused by inadequately labeled ethylene dichloride emulsion sold to control peach tree borers); *McCrossin v. Noyes Bros. & Cutler*, 173 N.W. 566 (Minn. 1919) (wrongful death action against dealer of "Roach Doom" based on allegedly inadequate label); *Mossrud v. Lee*, 157 N.W. 758 (Wis. 1916) (action for harm caused by inadequately labeled "Quack Grass Destroyer").

30. 7 C.F.R. Part 162 (1949). Those regulations, issued by the Secretary of Agriculture pursuant to 7 U.S.C. 135d, established that every pesticide label must prominently contain certain features, including the name and address of the manufacturer, the net contents of the pesticide, an "ingredient statement" providing the names and percentages of active and inert ingredients, directions for use, and

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uniformly concluded that the federal pesticide labeling regulations did not alter the availability of state law damages actions for inadequate labeling. A 1962 annotation of cases addressing the liability of agricultural chemical manufacturers stretches over 80 pages and restates the prevailing rule: "It is patent that a manufacturer of animal feed or medicine, or of an insecticide, or of other similar products, may, in some circumstances be held to a duty to give warning regarding his product."[31]

Case law uniformly recognized that FIFRA's labeling requirements did not conflict with the obligation to pay

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certain cautionary or warning statements. 7 C.F.R. 162.6, 162.7, 162.103 (1949). The regulations included requirements specifying the size, typeface, and position of the required pesticide label features. See, e.g., 7 C.F.R. 162.102 (1949) (product name); 7 C.F.R. 162.103 (1949) (ingredient statement); 7 C.F.R. 162.104 (1949) (net contents); 7 C.F.R. 162.105 (1949) (directions for use). Pesticides found to be highly toxic under 7 C.F.R. 162.8 (1949) were required to bear a label with the skull and crossbones symbols, the word "poison" in red lettering against a contrasting background, and provide emergency precautions. 7 C.F.R. 162.6, 162.9 (1949). The regulations further established pesticide-specific warning statements. See, e.g., 7 C.F.R. 162.112 (1949) (benzene hexachloride); 7 C.F.R. 162.113 (1949) (household fly sprays); 7 C.F.R. 162.114 (1949) (DDT). With various additions, those labeling requirements continued in force at the time that Congress enacted section 136v(b) and continue in force today. See 7 C.F.R. Part 2762 (1971); 7 C.F.R. Part 156 (1998).

31. Annotation, "Liability of Manufacturer or Seller for Injury Caused by Animal Feed or Medicine, Crop Sprays, Fertilizers, Insecticides, Rodenticides, and Similar Products," 81 A.L.R.2d 147 (1962).

damages in tort law for failure to warn. Thus, in a wrongful death action against an insecticide manufacturer, the First Circuit concluded that federal labeling approval "merely satisfied" federal law, but did not certify that defendant had met the standard of due care imposed by the state law. *Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402, 405 (1st Cir. 1965). The court plainly recognized that FIFRA did not occupy the field of pesticide regulation. *Ibid.* Far from preempting state tort law, FIFRA's labeling requirements were widely understood to set minimum standards of care without otherwise altering state common law.[32]

By 1972, when section 136v(b) was enacted, nearly every state and federal jurisdiction recognized pesticide

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32. See, e.g., *Griffin v. Planters Chem. Corp.*, 302 F. Supp. 937, 944 (D.S.C. 1969) ("Aside from the requirements set forth for the label by the Secretary of Agriculture, he had a duty to use a label, or furnish a warning commensurate with the danger."); *Gonzalez v. Virginia-Carolina Chem. Co.*, 239 F. Supp. 567, 572 (D.S.C. 1965) ("Even had the defendant not failed to warn the public as it was required to do by the Federal and State law, it is my opinion that the manufacturer of a hazardous material is under a common law duty to * * * give adequate warning."); *Muncy v. Magnolia Chem. Co.*, 437 S.W.2d 15, 19 (Tex. Ct. App. 1968) ("The statutes and regulations set minimum standards for those marketing economic poisons.") *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387, 394 (Tex. Ct. App. 1968) (FIFRA does not "purport[ ] to change the common law duty to warn. * * * We are of the view that [FIFRA and its regulations] merely set minimum standards."); *McClanahan v. California Spray-Chem. Co.*, 75 S.E.2d 712 (Va. 1953) (violation of FIFRA is negligence per se in state common law tort action); *Perry Creek Cranberry Corp. v. Hopkins Ag. Chem. Co.*, 139 N.W.2d 96, 102 (Wisc. 1966) (same).

manufacturer and dealer liability both for personal injuries and crop damage resulting from the failure to provide adequate warnings.[33] Courts uniformly agreed that such actions did not conflict with federal labeling requirements. In the absence of evidence that Congress intended to alter then-existing law, FIFRA should not be interpreted to do so.

2. FIFRA's legislative history reveals no intent to alter the availability of common law remedies.

Section 136v was enacted to delineate state regulatory authority, not to preempt existing state tort law. In 1971 and 1972, three House and Senate committees devoted 25 days to hearings on proposed pesticide legislation, the transcripts

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33. See, e.g., *Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402 (1st Cir. 1965) (applying Mass. law); *Grey v. Hayes-Sammons Chem. Co.*, 310 F.2d 291 (5th Cir. 1962) (applying Miss. law); *Daniels v. Atlantic Refining Co.*, 295 F. Supp. 125 (D. Del. 1968) (applying Delaware law); *Gonzalez v. Virginia-Carolina Chem. Co.*, 239 F. Supp. 567 (E.D. S.C. 1965) (applying South Carolina law); *Eaton Fruit Co. v. California Spray-Chem. Corp.*, 445 P.2d 437 (Ariz. 1968); *Diamond Alkali Co. v. Godwin*, 112 S.E.2d 365 (Ga. Ct. App. 1959); *Bean v. Diamond Alkali Co.*, 454 P.2d 69 (Idaho 1969); *Rose v. Buffalo Air Service*, 104 N.W.2d 431 (Neb. 1960); *Dole v. Dow Chem. Co.*, 316 N.Y.S.2d 348 (N.Y. Sup. Ct. 1970); *Corprew v. Geigy Chem. Corp.*, 157 S.E.2d 98 (N.C. 1967); *Stull's Chems., Inc. v. Davis*, 263 S.W.2d 806 (Tex. Ct. App. 1953); *McClanahan v. California Spray-Chem Corp.*, 75 S.E.2d 712 (Va. 1953); *Wise v. Hayes*, 361 P.2d 171 (Wash. 1961); *Perry Creek Cranberry Corp. v. Hopkins Ag. Chem. Co.*, 139 N.W.2d 96 (Wisc. 1966).

of which fill over 2,300 pages.[34] Each committee issued a report, filling over 275 pages.[35] A conference committee issued a 34-page report.[36] Floor debates occurred over five days, the transcript of which fills over 150 pages in the Congressional Record.[37] In those thousands of pages of

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34. Federal Pesticide Control Act of 1971: Hearings Before the House Comm. on Ag., 92d Cong., 1st Sess (1971) [hereinafter House Ag. Comm. hearing]; Federal Environmental Pesticide Control Act: Hearings Before the Subcomm. on Ag. Research of the Sen. Comm. on Ag. and Forestry, 92d Cong., 1st Sess. (1971) [hereinafter 1971 Sen. Ag. Comm. hearing]; Federal Environmental Pesticide Control Act: Hearings Before the Subcomm. on Ag. Research of the Sen. Comm. on Ag. and Forestry, 92d Cong., 2d Sess. (1972) [hereinafter 1972 Sen. Ag. Comm. hearing]; Federal Environmental Pesticide Control Act of 1971: Hearings Before the Subcomm. on the Environment of the House Comm. on Commerce, 92d Cong., 2d Sess. (1972) [hereinafter Sen. Commerce Comm. hearing].

35. H.R. Rep. No. 511, 92d Cong., 1st Sess. (1971) [hereinafter House Ag. Comm. report]; S. Rep. No. 838, 92d Cong., 2d Sess. (1972) [hereinafter Sen Ag. Comm. report]; S. Rep. No. 838 (Supplemental Report), 92d Cong., 2d Sess. (1972) [hereinafter Supplemental Sen. Ag. Comm. report]; S. Rep. No. 970, 92d Cong., 2d Sess. (1972) [hereinafter Sen. Commerce Comm. report].

36. H.R. Conf. Rep. No. 1540, 92d Cong., 2d Sess. (1972).

37. 117 Cong. Rec. 39,975-39,981 (Nov. 8, 1971) (House debate); 117 Cong. Rec. 40,020-40,068 (House debate and passage); 118 Cong. Rec. 32,448-32,263 (Sept. 26, 1972) (Sen. debate and passage); 118 Cong. Rec. 33,920-33,924 (Oct. 5, 1972) (Sen. passage of conference report); 118 Cong. Rec. 35,543-35,547 (Oct. 12, 1972) (House passage of conference report).

hearings, reports, and floor debates, there is no suggestion that the 1972 amendments to FIFRA would preempt state tort law.

a. The committee hearings. The most extensive discussion of what became section 136v occurred in the committee hearings, when the provision was first drafted. Testifying on behalf of the Administration and EPA, which drafted the bill that formed the basis of the 1972 amendments,[38] EPA's General Counsel emphasized that the bill was intended to authorize state agencies to continue to regulate pesticide use more strictly than the federal government:

> I would like to emphasize that the States have played a major and continuing role in pesticides regulation. * * * We wish to encourage and not supplant these efforts by providing that States may prohibit the use of a particular pesticide within their jurisdiction even if the pesticide is registered under the Federal authority. States thus are not precluded from imposing stricter standards or added requirements, but they may not permit any sale or use of a pesticide which is prohibited under the authority of the Act.

House Ag. Comm. hearing at 8 (statement of EPA General Counsel John Quarles).[39]

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38. See Sen. Ag. Comm. report at 9.

39. See also *id.* at 740 (statement of EPA Administrator William D. Ruckelshaus) ("I think [the federal government] ought (Cont'd)

Appendix E

As originally drafted, the Administration's bill did not include an express provision addressing the continuing regulatory authority of the states.[40] Representatives of state agencies feared, however, that the absence of a provision expressly preserving state authority might be construed to oust them completely from any regulatory role, notwithstanding a contrary congressional intent. The representative of the National Association of State Departments of Agriculture thus stated: "It is our feeling that it will be better for Congress to clearly indicate its intentions in this bill rather than leaving this area a glaring omission and have a battery of fellow lawyers and courts trying to answer these questions later on."[41]

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to set certain base levels of use for the pesticides * * * and the States can set stricter limits if they so desire."); 1971 Sen. Ag. Comm. hearing at 293 (statement of EPA Administrator Ruckelshaus).

40. See S. 660, 92d Cong., 1st Sess. (1971), reprinted in 1971 Sen. Ag. Comm. hearing at 7-110; H.R. 4152, 92 Cong., 1st Sess. (1971), reprinted in House Ag. comm. hearing at 859-904.

41. 1971 Sen. Ag. Comm. hearing at 338. See also House Ag. Comm. hearing at 517 (statement of Dr. Charles P. Ellington) (unless the states' role is clarified "I can almost predict with certainty that in a matter of a few years, there will be no State registration programs at all"); *id.* at 851 (letter from H.L. Bruer, Tennessee Dept. of Ag.) ("[W]e do not believe that the pre-emption of the field of pesticide registration and management is either necessary or desirable."); 1971 Sen. Ag. Comm. hearing at 336 (statement of Dr. Ellington) (without amendment the bill "would completely preempt State registration and if enacted and enforced as written there would no longer be any
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Appendix E

Representatives of the pesticide manufacturers also advocated the inclusion of an express provision clarifying the role of the state agencies.[42] They were concerned that state authority to regulate pesticide sales and use more strictly than the federal government might be construed to authorize state agencies to impose labeling regulations. One witness described the problems that might result from conflicting state regulations: "Some states might want the word 'flammable,' some 'inflammable.' * * * Some States might want red lettering; others orange, another yellow, and so

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need for State registration laws"); *id.* at 486 (statement of W.A. Ruffin, Alabama Dept. of Ag.) (expressing concern that the "implication" of the bill is that the "Federal Government is the only agency in the Nation competent to handle" pesticide regulation); *id.* at 494 (statement of John Kirkpatrick, Alabama Dept. of Ag.) (stating that the bill should be clarified to give states the right to enact stricter regulations than the minimum federal standard); *id.* at 498 (statement of J.R. Conley, Georgia Dept. of Ag.) (expressing concern about the implication of federal preemption of state regulation).

42. See House Ag. Comm. hearings at 334 (statement of Parke C. Brinkley, President, National Agricultural Chemicals Assn.) ("[T]here should also be included in the bill a determination that it preempts the field of pesticide regulations."); *id.* at 355 (stating that a preemption provision would clarify that FIFRA establishes "a minimum standard" and that "some States will want greater enforcement"); 1971 Sen. Ag. Comm. hearing at 418 (statement of Parke C. Brinkley, President, National Agricultural Chemicals Assn.) ("Congress should find that this system preempts the field of pesticide regulation subject to * * * authorizing State officials to impose additional regulatory requirements.").

forth."[43] In other testimony, pesticide manufacturers asserted that uniform labeling would alleviate the expense of producing multiple labels.[44] EPA agreed that there was a need for uniformity.[45]

Representatives of both the pesticide manufacturers and the state agriculture agencies submitted proposed preemption

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43. House Ag. Comm. hearing at 282-283 (statement of Robert L. Ackley); 1971 Sen. Ag. Comm. hearing at 510 (statement of Arthur B. Chivvis, President of Chemical Specialties Manufacturers Assn.); *id.* at 509 (same).

44. 1971 Sen. Ag. Comm. hearing at 509 (statement of Arthur B. Chivvis) ("The next portion of this bill that we would like to consider with the committee is the need for uniformity in the labeling and registration of household pesticides. Aerosol cans are usually lithographed, a rather expensive process * * *. To invite States to ignore the Federal registration and impose their own separate requirements on the label of these products would create a nightmare.").

45. EPA Administrator William D. Ruckelshaus testified:

> A number of States are strengthening their [pesticide] programs * * *. If the Federal Government does not move ahead and modernize its pesticide legislation, there is a possibility that there will be a large number of differing pesticide regulatory programs in the country, causing problems for consumers and industry alike, because of the lack of uniform requirements in various jurisdictions.

1971 Sen. Ag. Comm. hearing at 297.

provisions.[46] Characterized by EPA as specifying "the pesticide regulatory authority retained by the States,"[47] the preemption provision enacted as 7 U.S.C. 136v represented a compromise acceptable to the pesticide manufacturers, the state regulators, and the Administration.[48] Section (a) effectuates EPA's intent to authorize states to regulate the sale and use of pesticides more strictly than the federal government. Section (b) effectuates the pesticide manufacturers' desire to prohibit states from imposing labeling requirements in addition to, or different from, those imposed by EPA. And section (c) carries forth the state regulatory agencies' desire for authority to register pesticides for local uses not authorized by EPA.[49]

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46. See House Ag. Comm. hearing at 344 (amendment submitted by the National Agricultural Chemicals Assn.); *id.* at 829 (amendment submitted by Errett Deck, Wash. Dept. of Ag.). See also *id.* at 796 (amendment submitted by the American Frozen Food Institute).

47. 1972 Sen. Ag. Comm. hearing at 93.

48. See 1972 Sen. Ag. Comm. hearing at 93 (statement of David D. Dominick, EPA Assistant Administrator); *id.* at 153-154 (statement of Charles H. Frommer, New York Dept. of Environmental Conservation) ("We very strongly favor the provision of section 24(b) which provides for uniform labeling."); Sen. Commerce Comm. hearing at 135 (statement of David A. Phillipson, Vice President, National Agricultural Chemicals Assn.).

49. See H.R. 10729, 92d Cong., 2d Sess. § 24 (1972), reprinted in 1972 Sen. Ag. Comm. hearing at 69-70.

The hearings reveal that Congress had no intent to preempt state tort law. EPA's General Counsel, testifying as the first witness in the first hearing, stated unequivocally: "The bill does not affect tort liability."[50] No one disagreed. No witness or Member of Congress suggested that FIFRA would alter common law duties or affect the availability of tort damages. In three other instances, pesticide industry representatives mentioned, offhandedly, that product liability lawsuits had been brought against their companies,[51] but none of the 250 witnesses, including the 36 pesticide industry witnesses, or any Member of Congress, suggested that Congress should protect the pesticide industry from such actions. Thus, in 2,389 pages of committee hearing transcripts, the subject of common law tort actions was raised exactly five times, and not once in the context of preemption. The discussion of preemption, in contrast, exclusively

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50. House Ag. Comm. hearing at 42. The statement responded to a question posed by House Agriculture Committee Chairman W.R. Poage, which Mr. Quarles understood as being directed at state tort law but which Rep. Poage clarified was addressed to FIFRA's statutory civil penalties.

51. See House Ag. Comm. hearing at 415 (statement of John G. Kuniholm, Senior Counsel for Hercules, Inc.); 1971 Sen. Ag. Comm. hearing at 467 (statement of William L. Brehm, President, United Pesticide Formulators & Distributors Assn.); *id.* at 505 (statement of Ralph E. Heal, Executive Secretary, National Pest Control Assn.). In addition, a witness appearing on behalf of migrant farmers suggested that EPA regulations "facilitate the conduct of law suits" by providing "some evidence of what the standard of care is." 1971 Sen. Ag. Comm. hearing at 314 (statement of Kevin Carey, Deputy Director, Migrant Legal Program).

addressed the ongoing regulatory authority of state administrative agencies.

b. The committee reports. The four House and Senate Committee reports describe in detail the changes that the 1972 amendments would bring to federal pesticide regulation. The reports agree that "[t]he thrust of these amendments is to change FIFRA from a labeling law into a comprehensive regulatory statute that will henceforth more carefully control the manufacture, distribution, and use of pesticides."[52] The reports discuss the continuing authority of state agencies to regulate pesticide use[53] and emphasize that the amendments establish a "coordinated Federal-State administrative system to carry out the new program."[54] In this scheme, states have prime enforcement responsibility and "the Federal Government sets the program standards."[55]

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52. House Ag. Comm. report at 1. See also Sen. Ag. Comm. report at 1-2; Sen. Commerce Comm. report at 8.

53. See House Ag. Comm. report at 1-2, 16, 28; Sen. Ag. Comm. report at 2, 30; Supplemental Report of the Comm. on Ag. and Forestry, 92d Cong., 2d Sess. 51-52 (1972); Sen. Commerce Comm. report at 7, 29-30, 44.

54. House Ag. Comm. report at 1. See also Sen. Ag. Comm. report at 2, 29-30; Sen Commerce Comm. report at 44.

55. House Ag. Comm. report at 1. See also *id.* at 16 ("[T]he States would also be precluded from adopting programs which are less stringent than the Federal standards."); *id.* at 28 ("Generally, the intent of the provision is to leave the States the authority to impose stricter regulation on pesticides use than that required under the Act."); Sen. Ag. Comm. report at 30; Sen. Commerce Comm. report at 7, 29, 44.

Each report summarizes the changes made by the bill, but none mentions any intent to preempt state damages actions.[56]

The reports barely touch on the preemption of state authority to impose additional or different labeling requirements. Each of the Senate reports contains only a single sentence on the subject: "Subsection (b) preempts any State labeling or packaging requirement differing from such requirements under the Act."[57] The House Agriculture Committee report contains two additional sentences: "State authority to change Federal labeling and packaging is completely preempted. * * * [T]he Committee has adopted language which is intended to completely preempt State authority in regard to labeling and packaging."[58]

The House Agriculture Committee's intention to "completely preempt" state labeling authority cannot reasonably be read to express a congressional intent to extinguish damages actions. First, the committee's preemption discussion exclusively addressed the preemption of state regulatory authority without remotely addressing the

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56. See House Ag. Comm. report at 1-2, 12-13; Sen. Ag. Comm. report at 1-2, 5-6; Sen. Commerce Comm. report at 8.

57. Sen Ag. Comm. report at 30; Sen. Commerce Comm. report at 44.

58. House Ag. Comm. report at 1-2, 16. The Conference Committee Report to the 1972 amendments contains no mention of state authority under the amendments, the preemption provision, or state common law. H.R. Conf. Rep. No. 1540, 92d Cong., 2d Sess. (1972).

preemption of damages actions. Second, under the case law in 1972, state common law damages actions were not interpreted to impose labeling requirements. Third, as discussed below, Congress ultimately rejected the preemption provision written by the House Agriculture Committee that would have diminished the states' authority to regulate pesticide sales and use. The preemption provision adopted as section 136v is the Senate's, not the House committee's. Furthermore, pursuant to the preemption provision enacted by Congress, states may approve local uses of pesticides in addition to those approved by EPA and may impose supplementary labeling requirements regarding those additional uses. See 40 C.F.R. 162.153(e). Thus, it is simply not true that FIFRA completely preempts state labeling authority.

c. The floor debates. The House and Senate debated the 1972 FIFRA amendments over five days.[59] Like the committee hearings and reports, the floor debates reveal no suggestion of a congressional intent to preempt state tort law.

The preemption provision was not mentioned on the floor of the Senate. Summarizing the amendments,[60] no Senator

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59. See 117 Cong. Rec. 39,975-39,981 (Nov. 8, 1971) (House debate); 117 Cong. Rec. 40,020-40,068 (House debate and passage); 118 Cong. Rec. 32,448-32,263 (Sept. 26, 1972) (Sen. debate and passage); 118 Cong. Rec. 33,920-33,924 (Oct. 5, 1972) (Sen. passage of conference report); 118 Cong. Rec. 35,543-35,547 (Oct. 12, 1972) (House passage of conference report).

60. See 118 Cong. Rec. 32,256 (Sept. 26, 1972) (statement of Sen. Allen) ("Mr. President, this bill does two things. First, it

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mentioned the preemption of state tort law. The preemption provision was, however, debated at length on the floor of the House. Unlike the Senate bill, the House bill would have prohibited states from regulating certain pesticides more strictly than EPA.[61] An amendment was adopted eliminating the restriction.[62] Nowhere in the debate on the amendment is there a suggestion that the preemption provision would affect state tort law.

The House debate on another provision, section 136m, demonstrates that Congress anticipated the availability of state damages actions for the harms caused by pesticides. Section 136m requires the government, upon canceling pesticide registration, to indemnify pesticide manufacturers, dealers, and users, for the cost of purchasing pesticides made unusable by the cancellation. Several House Members feared that the indemnity provision would transform the United

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provides for regulating the use of pesticides, as distinguished from their labeling and interstate distribution. Second, it extends pesticide regulation to interstate commerce."). See also 117 Cong. Rec. 39,975 (Nov. 8, 1971) (statement of Rep. Sisk); *ibid.* (statement of Rep. Latta); 117 Cong. Rec. 39,976-39,977 (Nov. 8, 1971) (statement of Rep. Poage); 117 Cong. Rec. 40,067 (Nov. 9, 1971) (statement of Rep. Mizell); 118 Cong. Rec. 32,256 (Sept. 26, 1972) (statement of Sen. Allen); *id.* at 32,260; 118 Cong. Rec. 35,545 (Oct. 12, 1972) (statement of Rep. Kyl).

61. See 117 Cong. Rec. 40,027 (Nov. 9, 1971) (reprinting committee bill).

62. 117 Cong. Rec. 40,065 (Nov. 9, 1971).

States into an insurer of pesticides.[63] Proponents of the indemnity provision assuaged this fear by explaining that the indemnity payment would cover only the costs of owning unusable products[64] and would not insure against common law tort actions: "It has nothing to do with losses they might have suffered because of any damage done by the pesticides through food and fiber to their neighbors or someone down the street."[65]

Rather than reveal an intent to extinguish existing state-law damages remedies, the legislative history of the 1972 FIFRA amendments is replete with evidence that Congress understood and intended that state damages actions would remain available.

D. Preemption of State Tort Law Would Conflict with the Purposes of the 1972 FIFRA Amendments

The 1972 FIFRA amendments were enacted to address growing public concern with the environmental and public

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63. See 117 Cong. Rec. 40,046 (Nov. 9, 1971) (statement of Rep. Evans); 117 Cong. Rec. 40,050 (Nov. 9, 1971) (statement of Rep. Dickinson); 117 Cong. Rec. 40,055 (Nov. 9, 1971) (statement of Rep. Brasco).

64. 117 Cong. Rec. 40,051 (Nov. 9, 1971) (statement of Rep. Poage); 117 Cong. Rec. 40,052 (Nov. 9, 1971) (statement of Rep. Teague); 117 Cong. Rec. 40,053 (Nov. 9, 1971) (statement of Rep. Abernathy);

65. 117 Cong. Rec. 40,052 (Nov. 9, 1971) (statement of Rep. Teague).

health effects of pesticides such as DDT. As the Senate Agriculture Committee report explains, "The bill provides for the more complete regulation of pesticides in order to provide for the protection of man and his environment and the enhancement of the beauty of the world around him."[66] Congress knew of the harms caused by pesticides: the committees heard different estimates of the number of deaths and injuries attributable to pesticides, ranging from 200 to 800 deaths per year, and 60,000 to 80,000 injuries.[67] Congress was also aware that state damages actions provided a remedy for those injuries, meaning that FIFRA need not provide a private cause of action for damages. Likewise, FIFRA does not establish an exclusive federal enforcement scheme. Instead, FIFRA delegates to the states primary enforcement responsibilities. See 7 U.S.C. 136w-1.

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66. Sen. Ag. Comm. report at 3. See also Sen. Commerce Comm. report at 9 ("[S]ociety has become increasingly sensitive to the abuses certain pesticides have inflicted upon man and the environment.")

67. See House Ag. Comm. hearing at 708 (statement of Russell Train, Chairman, President's Council on Environmental Quality) (estimating that pesticides were involved in 200 deaths and 60,000 injuries a year); Sen. Ag. Comm. hearing at 161 (same); *id.* at 168-171 (reprinting Wayland J. Hayes, "Occurrence of Poisoning by Pesticides"); *id.* at 172-186 (reprinting Wayland J. Hayes, "Mortality from Pesticides in 1961"); *id.* at 506 (National Pest Control Association analysis of pesticide-related accidents); Sen. Commerce Comm. hearing at 87 (statement of A.V. Krebs, Agribusiness Accountability Project) (discussing harms caused by parathion); *id.* at 96 (statement of Sen. Nelson) (discussing pesticide poisoning case); *id.* at 170 (statement of Sen. Inouye) (discussing studies of nerve damage caused by pesticides).

These three facts — the absence of a federal private damages remedy, Congress's awareness of state damages remedies, and Congress's decision to give the states the primary enforcement authority under FIFRA — strongly imply that Congress did not intend to preempt state common law damages remedies.[68] Given that the 1972 amendments to FIFRA were intended to provide *increased* public protection against the harms caused by pesticides, it would make no sense to infer that Congress intended to close off all avenues of judicial relief for those injured by pesticides.

The *Medtronic* plurality rejected similar arguments in interpreting the MDA. Absent a federal private cause of action, preemption of state damages actions would effectively bar relief to persons injured by defective medical devices and "have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation * * *." 518 U.S. at 487. Such an interpretation contravened Congress's purpose and intent:

> It is to say the least, "difficult to believe that Congress would, without comment, remove all

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68. Compare *American Airlines, Inc. v. Wolens*, 513 U.S. 219 (1995) (finding that, because the Airline Deregulation Act does not establish exclusive federal remedies, state common law actions are not preempted) with *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 143-145 (1990) (finding that ERISA's comprehensive civil enforcement scheme supports preemption of common-law wrongful discharge claims). Cf. *Oneida County, N.Y. v. Oneida Indian Nation*, 470 U.S. 226, 236-237 (1985) (federal statutes do not extinguish federal common law unless "the statute speaks directly to the question otherwise answered by federal common law").

> means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984), and it would take language much plainer than the text of § 360k to convince us that Congress intended that result.

518 U.S. at 487. Similarly, Congress did not anticipate that FIFRA would eliminate relief for persons harmed by pesticides. FIFRA's preemptive force should not be interpreted to undermine the statutory purpose to provide increased protection from harmful pesticides.

II. SECTION 136v(b) DOES NOT PREEMPT COMMON LAW ACTIONS ADDRESSING MATTERS SUCH AS PESTICIDE EFFICACY UNREGULATED BY EPA

Even if FIFRA's prohibition on state labeling "requirements" can be read to preempt some state damages actions, it cannot be read to preempt damages actions regarding pesticide efficacy[69] because such actions do not impose labeling requirements "in addition to or different from" those imposed by FIFRA. FIFRA contains a general prohibition against "misbranding" of pesticide labels, which establishes that a label violates FIFRA if it is "false or misleading," contains inadequate "directions for use," or omits a necessary "warning or caution statement." 7 U.S.C.

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69. The efficacy of pesticides depends on two variables: (1) whether the pesticide controls the target pest and (2) whether the pesticide does no harm to the target crop. EPA refers to the first aspect of efficacy as "product performance," 40 C.F.R. 158.640(b), and the second aspect as "phytotoxicity." 40 C.F.R. 158.540.

136(q). In registering pesticides, EPA evaluates whether label statements addressing human health and the environment comply with the misbranding prohibition. With express congressional approval, however, EPA registers pesticides without evaluating the truthfulness or adequacy of label statements addressing pesticide efficacy, including any warnings that address potential crop damage. In the absence of federal evaluation of efficacy statements, the only applicable federal "requirement" governing such statements is the general prohibition against misbranding. Because the common law duty to warn imposes nearly identical obligations,[70] the common law duty is not "in addition to or different from" a federal requirement and thus is not preempted by FIFRA.

In *Medtronic*, the Supreme Court unanimously agreed that, when state law parallels federal law, state law is not "different from, or in addition to" federal law and therefore is not preempted under the MDA. As the plurality stated, the MDA does not preempt state authority "to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495. The dissent similarly concluded that "[t]o be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed

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70. See Restatement (Third) of Torts § 2 (1998) ("A product * * * is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.").

on them under state and federal law do not differ." *Id.* at 513 (O'Connor, J., dissenting). See also *id.* at 505 (Breyer, J., concurring).[71] Applying the *Medtronic* Court's unanimous conclusion here, when state law parallels the requirements imposed under FIFRA, state law cannot be characterized as imposing requirements "in addition to or different from" federal requirements. Because the state duty to warn parallels the federal misbranding prohibition, it is not preempted by section 136v(b).

Furthermore, because EPA registers pesticides without evaluating efficacy claims, preemption of state damages

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71. In his concurrence in *Medtronic*, Justice Breyer concluded that the MDA's preemption of state authority to impose requirements "different from, or in addition to" requirements imposed under the MDA only precludes states from imposing requirements on the same subjects as federal requirements:

> The words "any [state] requirement" and "any [federal] requirement," for example, do not tell us which requirements are at issue, for every state requirement that is not identical to even one federal requirement is "different from, or in addition to" that single federal requirement; yet, Congress could not have intended that the existence of one single federal rule, say, about a 2-inch hearing aid wire, would pre-empt every state law hearing aid rule, even a set of rules related only to the packaging or shipping of hearing aids. Thus, Congress must have intended that courts look elsewhere for help as to just which federal requirements pre-empt just which state requirements, as well as just how they might do so.

518 U.S. at 505 (bracketed material supplied by Justice Breyer).

actions challenging pesticide efficacy statements would leave such statements largely, or entirely, unregulated. That result would contravene congressional intent. In authorizing EPA to waive the review of pesticide efficacy claims, Congress anticipated that the *states* would regulate pesticide efficacy. Following Congress's lead, EPA waived its review of pesticide efficacy claims, finding that state tort law adequately polices pesticide claims of efficacy. No evidence suggests that Congress or EPA had any intent to leave the area of pesticide efficacy unregulated.

A. EPA Does Not Evaluate Pesticide Efficacy

The conclusion by some courts that FIFRA preempts all damages actions challenging the adequacy of pesticide warnings relies on the mistaken notion that FIFRA regulates all aspects of pesticide labeling.[72] The same mistake is repeated by many amici in their briefs to this Court.[73] In fact,

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72. See, e.g., *Taylor AG Industries v. Pure-Gro*, 54 F.3d 555, 560 (9th Cir. 1995) (finding preemption given FIFRA's "rigorous label-approval process"); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir. 1993) (finding that preemption is necessary "[g]iven the comprehensive nature of the FIFRA labeling process"); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1179 (10th Cir. 1993) ("We believe Congress circumscribed the area of labeling and packaging and preserved it only for federal law."); *King v. E.I. DuPont de Nemours*, 996 F.2d 1346, 1347 (1st Cir. 1993) ("The EPA has promulgated comprehensive labeling requirements governing the scope, content, wording and format of herbicide labeling.").

73. See, e.g., Brief of American Crop Protection Assn. at 8 ("The EPA Administrator then undertakes a comprehensive review of all pertinent data * * *.").

with few exceptions, EPA has not regulated pesticide efficacy claims for almost 20 years.

Although the 1972 amendments to FIFRA required EPA to evaluate all claims made on a pesticide label, a 1978 amendment allows EPA to limit the scope of its review. The 1972 amendments mandated that EPA register a pesticide only upon evaluating a proposed pesticide label and determining that the pesticide's "composition is such as to warrant the proposed claims for it." 7 U.S.C. 136a(5)(A). After the enactment of the 1972 amendments, however, it immediately became clear that the pesticide approval process was overly cumbersome. As the House Agriculture Committee stated, "The registration and reregistration process, which is the foundation of the program, has come to a virtual halt." H. Rep. No. 95-663, 95th Cong., 1st Sess. 18 (1977), reprinted in 1978 U.S.C.C.A.N. 1991. EPA lacked the resources to review the veracity of all proposed labeling statements. Specifically, EPA reported to Congress that the resources required to evaluate efficacy claims detracted from its ability to devote resources to health and environment concerns. See H. Rep. 95-343, 95th Cong., 1st Sess. 9, reprinted at 1978 U.S.C.C.A.N. 1974 (statement of EPA Administrator Douglas M. Costle).

In response to these concerns, Congress amended FIFRA in 1978 by, inter alia, expressly granting EPA the authority to waive review of pesticide efficacy claims:

> In considering an application for the registration of a pesticide the Administrator may waive data requirements pertaining to efficacy, in which

> event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

7 U.S.C. 136a(c)(5). Congress did not merely authorize EPA to waive review of efficacy data; it encouraged EPA to do so. See H. Rep. No. 95-663, 95th Cong., 1st Sess. 19 (1977), reprinted in 1978 U.S.C.C.A.N. 1992 ("This authority is expected to be used, in particular with respect to agricultural chemicals.").

Congress did not, however, intend to leave pesticide efficacy unregulated. On the contrary, Congress specifically sanctioned *state* regulation of pesticide efficacy. The efficacy-review waiver provision thus establishes a presumption that where a *state* has found a pesticide to be efficacious, EPA need not review efficacy claims. Congress directed EPA not to second-guess state efficacy review, not vice versa. Alternatively, absent state review, EPA could waive efficacy review as long as it found that "some other procedure for assuring the efficacy of pesticide products appeared to be sufficient." *Id.* at 27, reprinted in 1978 U.S.C.C.A.N. 2000.

Effectuating Congress's intent, EPA issued a general waiver of the review of labeling claims relating to pesticide

efficacy. 40 C.F.R. 158.640(b);[74] 40 C.F.R. 158.540. EPA explained that the waiver would enable it to focus on its "primary mandate under FIFRA * * * the health and safety aspects of pesticides." 47 Fed. Reg. 53192 (Nov. 24, 1982). EPA concluded that efficacy review was unnecessary because efficacy claims are "effectively regulated by the marketplace." 44 Fed. Reg. 27932 (May 11, 1979), and "pesticide producers are aware that they are potentially subject to damage suits by the user community if their products prove ineffective in actual use," 47 Fed. Reg. 40659, 40661 (Sept. 15, 1982). In finding that the pesticide market and damages liability effectively regulate pesticide efficacy, EPA precisely followed Congress's direction to waive efficacy review if it found that "some other procedure for assuring the efficacy of pesticide products appeared to be sufficient." 1978

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74. EPA regulations provide:

> The Agency has waived all requirements to submit efficacy data unless the pesticide bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

40 C.F.R. 158.680(b)(1).

U.S.C.C.A.N. 2000. As a result of the waiver, EPA only reviews pesticide labels for the adequacy of claims relating to human health and the environment.[75]

Despite EPA's express waiver, defendants and amici argue that EPA continues to regulate efficacy-related label statements. First, defendants point to the registration criterion that requires EPA to determine that the pesticide will not have "unreasonable adverse effects on the environment." 7 U.S.C. 136a(c)(5). Because FIFRA defines the term "environment" to include "all plants," 7 U.S.C. 136(j), defendants argue that harm to the "environment" includes harm to crops. That argument is without merit. The definition of "environment" does not alter EPA's statutory authority, and express decision, to waive its evaluation of pesticide efficacy data in registering pesticides. 7 U.S.C. 136a(c)(5). Moreover, Congress's primary concern in enacting the 1972 FIFRA amendments was to protect the *natural* environment from the harms caused by pesticides such as DDT.[76] In

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75. EPA continues to review pesticide labels with regard to one category of efficacy claims: claims made on the labels of products such as microbial disinfectants that are designed to control pests that pose a threat to human health. 40 C.F.R. 158.640(b). Congress understood that EPA would continue to evaluate that limited set of efficacy claims. See H. Rep. No. 343, 95th Cong., 1st Sess. 9 (1977), reprinted in 1978 U.S.C.C.A.N. 1974 ("It is important for EPA to carefully assess efficacy in certain cases, such as hospital disinfectants, where public health is at stake.") (statement of EPA Administrator Costle).

76. Thus, the House Agriculture Committee report states that "pesticides are valuable to our Nation's agricultural production * * *, (Cont'd)

administering FIFRA, EPA has similarly focused primarily on protection of the *natural* environment.[77]

Second, defendants cite to EPA's authority to regulate efficacy-related label claims. EPA readily admits that its FIFRA authority is broad and that it can consider efficacy-related matters in determining whether to continue the registration of a pesticide. The mere fact that EPA has *authority* to impose efficacy-related requirements, however, does not preempt state action. Rather, section 136v(b) preempts state labeling requirements "in addition to or different from" requirements actually "required" under FIFRA.

Third, defendants argue that EPA regulates efficacy by requiring that a pesticide label contain adequate directions for use, including "[w]arnings as required against use on certain crops, animals, objects, or in or adjacent to certain area." 40 C.F.R. 156.10(i)(2)(x)(C). Similarly, defendants argue that EPA regulates plant toxicity because EPA's

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(Cont'd)
but it is essential to the public health and welfare that they be regulated closely to prevent adverse effects on human life and the environment, including pollution of interstate and navigable waters." House Ag. Comm. report at 14. The example chosen to represent harm to the environment — water pollution — clearly indicates that Congress's primary focus was in protecting the natural environment.

77. See 49 Fed. Reg. 42856, 42873-42874 (1984) ("[T]he Agency's major concern with respect to phytotoxicity is with unintentional damage to *natural* plant populations.") (emphasis added).

internal manual on labeling requires that the directions for use contain specific plant application and plant toxicity information. It is true that the regulation requires pesticide manufacturers to include warnings on potential crop damage, but EPA only evaluates the adequacy of such warnings with respect to pesticides designed to protect human health.[78] With respect to other pesticides, such as those at issue in this case, FIFRA imposes only general requirements that efficacy statements be accurate, see 7 U.S.C. 136(q); as discussed above, the state law duty to provide adequate warnings almost exactly parallels the federal duty and thus is not "in addition to or different from" the federal requirements under 7 U.S.C. 136v(b).

Fourth, defendants argue that EPA regulates efficacy by requiring manufacturers to report toxic or adverse incidents including data on any "alleged effect involving damage to plants." 40 C.F.R. 159.184(c)(5)(iv). EPA's authority to require adverse incident reports derives from 7 U.S.C. 136d(a)(2), which imposes an ongoing obligation on manufacturers of registered pesticides to provide new information "regarding unreasonable adverse effects on the environment of the pesticide." Pursuant to that section, EPA requires manufacturers to report information learned after registration that indicates that a pesticide may have environmental effects not considered in the registration process. A requirement to *provide data* on the adverse

78. EPA's label review manual does mention reviewing labels regarding phytotoxicity concerns. Label Review Manual at 11-8. However, this is appropriate given that EPA requires the submission of phytotoxicity data bearing on *environmental* issues. See 40 C.F.R. 158.540. As noted, EPA has waived phytotoxicity data on crop damage issues. Id.

environmental effects of registered pesticides, however, does not amount to a *labeling* requirement. Moreover, an adverse incident report regarding harm to crops caused by a pesticide may indicate potential environmental harms caused by the pesticide.

In short, defendants' citations to FIFRA, EPA regulations, and the EPA pesticide registration manual cannot alter the fundamental fact: EPA has waived the review of efficacy data in approving pesticide labels.

B. Congress Did Not Intend to Leave Pesticide Efficacy Unregulated

Congress rarely preempts state law without providing federal law to fill the gap. The Supreme Court has repeatedly cautioned that courts should find that preemption leaves an area unregulated only where the evidence clearly demonstrates that Congress made a deliberate decision to do so.[79] Here, the evidence clearly demonstrates that Congress did not intend to leave claims of pesticide efficacy unregulated. As section 136a(c)(5) provides, Congress anticipated that *states* would continue to have authority to

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79. Compare *International Assn. of Machinists v. Wisconsin Employment Relations Comm'n*, 427 U.S. 132, 145 (1976) (finding that in the National Labor Relations Act "Congress meant to leave some activities unregulated and to be controlled by the free play of economic forces") with *Arkansas Elec. Coop. Corp. v. Arkansas Public Serv. Comm'n*, 461 U.S. 375, 384 (1983) (finding that "nothing in the language, history, or policy of the Federal Power Act suggests" * * * "an authoritative federal determination that the area is best left unregulated").

evaluate claims of pesticide efficacy under section 136v(c). Moreover, Congress instructed EPA to waive efficacy data review if it found that "some other procedure for assuring the efficacy of pesticide products appeared to be sufficient." 1978 U.S.C.C.A.N. 2000. EPA did exactly that, finding that the pesticide market and state damages actions provide sufficient safeguards to ensure pesticide efficacy.

Interpreting section 136v(b) to preempt state damages actions challenging label claims regarding pesticide efficacy creates a dilemma for EPA unintended by Congress: to divert resources away from its primary mission of protecting human health and the environment in order to regulate pesticide efficacy or to let pesticide efficacy go unchecked knowing that states cannot fill this void. Because there is no evidence that, in enacting sections 136a(c)(5) and 136v(b), Congress had any intent to leave pesticide efficacy unmonitored, and because Congress wanted EPA to devote its limited resources to health and environment issues, FIFRA should not be interpreted as preempting state damages actions regarding pesticide efficacy.

III. FIFRA Does Not Preempt State Damages Actions Challenging Off-Label Statements

Even if FIFRA preempts some or all state law damage actions based on pesticide labeling, FIFRA cannot be read to preempt state damages actions for failure to warn based on representations made outside a pesticide label, such as claims made orally or in advertising. Because such actions do not challenge the adequacy of federally approved pesticide *labels* and impose no *labeling* requirements, they are not preempted by FIFRA.

Appendix E

In *Cipollone*, the four-Justice plurality squarely addressed this issue. The plurality held that state-law failure to warn claims were preempted by the 1969 Cigarette Act only to the extent that those claims concern areas of state authority preempted by the Act, i.e., a state-law "requirement or prohibition * * * with respect to * * * advertising or promotion." 505 U.S. at 524-525. Under this rule, the plurality concluded, duty-to-warn claims based on inadequate advertising or promotions were preempted, but duty-to-warn claims challenging a cigarette makers' actions unrelated to advertising or promotion, such as testing and research practices, were not preempted. *Ibid.* The possibility that future advertising or promotion might be affected by a state damages award for failure to warn based on testing, research, or some other action, did not render such claims preempted. The plurality reinforced this conclusion in finding express warranty claims not preempted: "The appropriate inquiry is not whether a claim challenges the 'propriety' of advertising and promotion, but whether the claim would require the imposition under state law of a requirement or prohibition * * * with respect to advertising or promotion." *Id.* at 525.

Just as the scope of the 1969 Cigarette Act was limited to advertising and promotion, FIFRA only restricts state authority as to labeling or packaging. FIFRA's definition of labeling is restricted to printed matter — on the label and accompanying the product. 7 U.S.C. 136a(p). Section 136v(b) thus does not preempt state common law actions for breach of express warranty, negligence, or failure to warn that are based on representations made by salespersons or advertisers. Assessing liability for false, misleading or negligent representations made outside the label simply

imposes no "labeling and packaging" requirements. Because FIFRA's narrow preemption provision only speaks to "labeling and packaging" requirements, FIFRA should not be interpreted to preempt claims based on off-label statements.

CONCLUSION

For the foregoing reasons, this Court should find that FIFRA does not preempt state-law failure to warn actions. This Court should also find that FIFRA does not preempt damages actions challenging label claims regarding pesticide efficacy and that FIFRA does not preempt damages actions challenging off-label representations regarding pesticides.

Respectfully submitted,

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MARCH 1999
90-12-01150

Appendix E

PROOF OF SERVICE BY MAIL
(Code Civ. Proc., §§1013a, 2015)

WASHINGTON, DC

I am employed in Washington, DC; I am over the age of 18 years and not a party to the within action; my business address is 601 D. St., NW, Room 8024, Washington, DC 20004.

On March 22, 1999, I served **APPLICATION BY THE UNITED STATES FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE OF THE UNITED STATES IN SUPPORT OF PLAINTIFFS-APPELLANTS** on the interested parties in this action by placing a true copy thereof, enclosed in a sealed envelope, postage prepaid, addressed as follows:

See Attached Service List

I am readily familiar with the business practice of my place of employment in respect to the collection and processing of correspondence, pleadings and notices for mailing with the United States Postal Service.

The foregoing sealed envelope was placed for collection and mailing this date consistent with the ordinary business practice of my place of employment, so that it will be picked up this date with postage thereon fully prepaid at Washington, DC, in the ordinary course of such business.

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on March 22, 1999, at Washington, DC.

s/ Anne Rachel Traum
Signature

Anne Rachel Traum
Print Name

Appendix E

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Appendix E

EPA
UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

Pesticide Regulation (PR) Notice 96-4

June 3, 1996

Pesticide Regulation (PR) NOTICE 96-4

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration and Reregistration of Pesticide Products

SUBJECT: Label Statements Involving Product Efficacy and Potential for Harm to Property

I. INTRODUCTION

This notice explains EPA procedures in approving pesticide labels that include claims relating to the efficacy of agricultural pesticides and provides a warning to growers regarding reliance on label statements regarding pesticide efficacy. EPA is issuing this notice at this time to correct a misunderstanding regarding the FIFRA label approval process and efficacy claims that is reflected in a series of court decisions concerning the preemptive effect of FIFRA.

Appendix E

II. LEGAL FRAMEWORK

A. Registration and the Label Approval Process

EPA approves pesticide labels in the process of registering a pesticide under FIFRA. FIFRA specifies that EPA shall register a pesticide if:

> (1) its composition is such as to warrant the proposed claims for it;
>
> (2) its labeling and other material required to be submitted comply with the requirements of this Act;
>
> (3) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (4) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. § 136c(c)(5). Although the first registration requirement identified above mandates that EPA consider efficacy of label claims, Congress, in 1978, explicitly gave EPA the authority to waive that requirement. FIFRA states:

> In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which

> event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy.

7 U.S.C. § 136c(c)(5). The legislative history explains that Congress believed that product performance issues for agricultural pesticides were adequately addressed by information from government and university sources and market forces:

> This authority [to waive efficacy data] will be used most commonly with respect to agricultural pesticides, due to the high level of knowledge concerning pesticidal efficacy that prevails in the agricultural community, the existence of means for communicating efficacy information to users, the organizational expertise of the Department of Agriculture, the extension services, and the universities in this area, and the stake the industry has in marketing products that are efficacious.

S. Rpt. 95-334, 95th Cong., 1st Sess. 20 (July 6, 1977).

EPA has acted under this authority to waive, by regulation, data requirements as to efficacy issues for all agricultural pesticides. 44 Fed. Reg. 27932 27938 (col. 3) (May 11, 1979); 40 CFR 158.640(b)(1); see also 47 Fed. Reg. 57624 (December 27, 1982). EPA concluded that agriculture pesticides are "effectively regulated by the marketplace," 44 Fed. Reg. 27932, 27938 (col. 3) (May 11, 1979), and that waiving review of the efficacy of agricultural

pesticides in the registration process would enable the Agency to focus of its "primary mandate under FIFRA": investigating "the health and safety aspects of pesticides." 47 Fed. Reg. 53192 (November 24, 1982); 47 Fed. Reg. 40659, 40661 (col.1) (September 15, 1982). EPA pointed to private legal actions for damages as one factor that would ensure that pesticide manufacturers sold an efficacious product: "pesticide producers are aware that they are potentially subject to damage suits by the user community if their products prove ineffective in actual use." 47 Fed. Reg. 40659, 40661 (col.2) (September 15, 1982).

EPA has also, by regulation, promulgated various requirements pertaining to pesticide labels. These regulations bar the registration of any pesticide with a misbranded label, 40 C.F.R. § 152.112(f), and contain specific examples of label statements that are considered false or misleading and thus render a label misbranded. 40 C.F.R. § 156.10(a)(5). Additionally, the regulations have requirements for warning statements and mandate that pesticide products have adequate use directions. 40 C.F.R. § 156.10(h) and (i).

B. State Preemption Under FIFRA

FIFRA permits states broad authority to regulate pesticides but makes it unlawful for states that undertake such regulation to "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act." 7 U.S.C. § 136v(b). A number of federal court decisions have held that this preemption of state authority as to pesticide labels bars damage claims in state court by growers against

pesticide manufacturers. The courts have reasoned that allowing such a claim by a grower would be, in effect, permitting the state to impose label requirements "in addition to or different from" the federally-approved label.

III. LABEL APPROVAL AND PESTICIDAL EFFICACY

There have been several recent preemption decisions involving claims by growers concerning pesticidal efficacy or property damage caused by a pesticide. For example, in Taylor Ag Industries v. Pure-Gro, 54 F.3d 555 (9th Cir. 1995), several growers sued the manufacturers and distributor of a pesticide that the growers alleged had damaged their cotton crop even though they had applied the pesticide according to the label directions. The court denied the growers' claims on the ground that allowing recovery of damages would interfere indirectly with EPA's "rigorous label-approval process." Id. at 560. In Welchert v. American Cyanamid, Inc., 59 F.3d 69 (8th Cir. 1995), and Worm v. American Cyanamid, Inc. 5 F.3d 744 (4th Cir. 1993), growers sued a pesticide manufacturer seeking recovery for harm to crops allegedly caused when the manufacturer's herbicide remained in the soil and damaged rotated crops. Both courts dismissed the growers' claims noting that EPA's labeling regulations required instructions on rotational crop restrictions. The courts reasoned that to permit such lawsuits "would be to allow state courts to sit, in effect, as super-EPA review boards that could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations." Welchert, 59 F.3d at 73; Worm, 5 F.3d at 749.

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These court decisions are based on the premise that, in approving labels for agricultural pesticides, EPA examines, or at least has the obligation to examine, the efficacy of the pesticide and related issues such as the potential for the pesticide to cause property damage. The courts, however, have not taken into account the plain language of the statute on this issue and have misinterpreted the thrust of EPA's regulations. As noted above, in actual fact, EPA, with Congress' approval, stopped evaluating pesticide efficacy for routine label approvals almost two decades ago. Further, as explained below, EPA's regulations do not require a review of efficacy of property damage issues for agricultural pesticides.

EPA's labeling regulations must be interpreted in light of the statutory requirements for registration and EPA's waiver of the requirement for efficacy data on agricultural pesticides. Because efficacy data is not reviewed as part of the registration of agricultural pesticides, it would be incorrect to contend that the label approval process involves an examination of the efficacy of the pesticide. Rather, the label approval process is centered on the issue of the whether label, including the specification of use sites and the directions for use on the label, meets the core requirement for registration: that the pesticide not cause "unreasonable adverse effects on the environment." That term is defined as "any unreasonable risk to man or the environment . . . ." 7 U.S.C. § 136(bb). Accordingly, the primary focus in the label approval process for agricultural pesticides involves assessing and regulating the potential risks to humans and the environment posed by such pesticides.

To this end, EPA applies the requirements in its labeling regulations with an eye to risk not efficacy issues. This is illustrated by how EPA applies label requirements regarding pesticide use sites and directions for the use of pesticides including directions concerning rotational crops. Label regulations require that pesticide use sites (e.g., specific crops, animals, etc.) be listed on the label because assessment of the dietary risk of pesticides is based on the foods that legally may contain the pesticide, and, under FIFRA, the label establishes the legal limits on use of a pesticide. 7 U.S.C. § 136j(a)(2)(G). Use sites are not reviewed as to the pesticide's efficacy for those crops. The label regulations address the directions for use of a pesticide for the purpose of insuring that pesticide applicators and farmworkers are adequately protected. Additionally, directions for use establish legal limits as to the amounts of pesticide that may be applied and thus allow EPA to control and estimate dietary exposure. EPA does not check to see whether application equipment mentioned in directions for use will be harmed or whether other property damage might occur. For example, the label regulations on directions for use specify that rotation crop restrictions are required when needed "to prevent unreasonable adverse effects upon the environment." 40 C.F.R. § 156.10(i)(2)(x). Such restrictions are needed for certain pesticides to prevent uptake of residual pesticide residues from the soil into crops for which the pesticide is not registered. EPA's concern is that the consumption of the rotated crop would increase dietary exposure to the pesticide residue. Rotational crop restrictions are not reviewed to determine if the rotated crop would be injured by the residual pesticide residues.

An additional requirement for registration, noted above, is that the pesticide's labeling comply with the Act. Separately, EPA, by regulation, has required that labeling not be misbranded. 40 C.F.R. § 152.112(f). However, these registration requirements should not be read as reintroducing efficacy concerns into the label approval process. Having directly given EPA the authority to disregard efficacy issues, Congress could not have intended that, once EPA exercised this authority, the same efficacy issues would come in through the back door of the label approval process. Under the statute and its regulations, EPA still must determine in registering a pesticide if the pesticide's label complies with FIFRA or is misbranded but, unless EPA reinstates the requirement to submit efficacy data (either generally or with regard to a particular pesticide), that compliance and misbranding inquiry will generally not extend to the evaluation of the efficacy of the pesticide.

Efficacy and property damage issues are at times relevant to the continued registration of a pesticide. FIFRA's "unreasonable adverse effects" standard requires EPA to take into account "economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb). A pesticide's efficacy and its potential to cause property damage are factors to be considered in determining the economic benefit a pesticide provides to farmers. However, in light of EPA's waiver of the efficacy data requirement for initial registration, these issues would generally only arise following the registration of the pesticide, including approval of the pesticide label. For example, if a pesticide manufacturer were to learn that one its registered pesticides was causing property damage, the manufacturer would be obligated to

report that information under section 6(a)(2) of the statute. 7 U.S.C. § 136c(a)(2). Additionally, if EPA discovers new risk concerns with an already-registered pesticide, it might examine efficacy data with regard to the pesticide in making an evaluation under the unreasonable adverse effects standard to determine if the product's registration should be cancelled or suspended.

IV. CONCLUSION

EPA hopes this Notice will be useful to courts, the regulated community, and pesticide users. EPA believes this Notice should be helpful to courts in preemption cases that involve EPA's labeling regulations. For example, some courts have mistakenly assumed that EPA's labeling regulations concerning the directions for use of a pesticide have an efficacy component. Further, other courts have erroneously concluded that because a pesticide label contained warnings regarding property damage that EPA had necessarily evaluated such warnings and found them to be truthful and adequate. As to registrants and applicants for registration, this Notice is intended to confirm that EPA has not altered its regulation relating to the waiver of efficacy data requirements for the registration of agricultural pesticides. Finally, as to pesticide users this Notice is intended to clarify that EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage.

Daniel M. Barolo
Director, Office of Pesticide
Programs

APPENDIX F — RELEVANT STATUTE

7 U.S.C. § 136v

TITLE 7 — AGRICULTURE

CHAPTER 6 — INSECTICIDES AND ENVIRONMENTAL PESTICIDE CONTROL

SUBCHAPTER II — ENVIRONMENTAL PESTICIDE CONTROL

Sec. 136v. Authority of States

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

(c) Additional uses

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration